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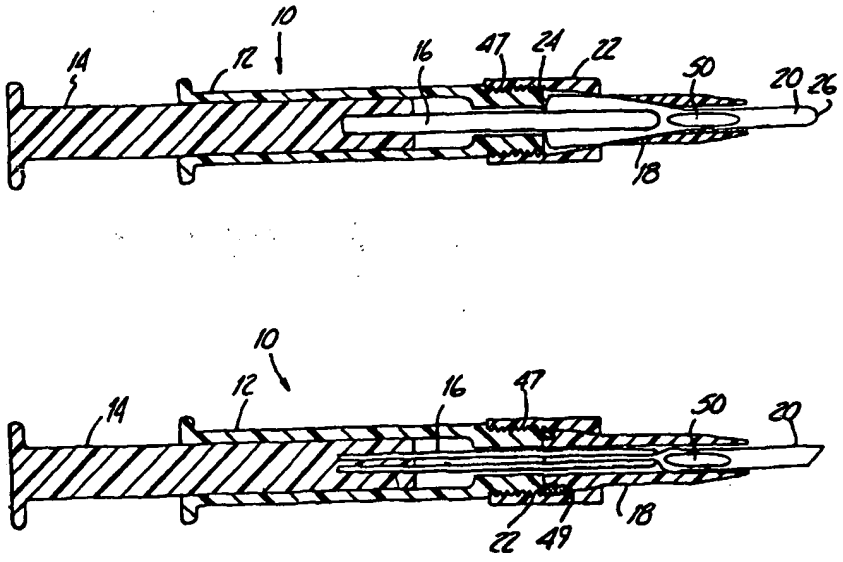

(57) Abstract

This invention discloses insertor devices that employ a flexible, deformable sleeve to house an implant. In one embodiment, a device is described that employs squeezing blades to advance an implant through the flexible sleeve into a passageway, tissue or cavity of the body. The invention further relates to holders for the sleeve to facilitate loading of an implant into the sleeve. In a preferred embodiment, the device is an insertor for a foldable lens and in particular the device is an insertor for the introduction of an intraocular lens into the eye. Methods for loading the devices of this invention with an implant, methods for making the sleeves of this invention and methods for use are discussed.

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OPHTHALMOLOGIC INSERTOR APPARATUS AND METHODS OF USE

Field of the Invention

The present invention relates to the field of implantation methods. Preferably, the invention relates to the field of ophthalmology and to the use of medical devices in ophthalmologic surgery. In a particularly preferred embodiment, the present invention relates to methods and procedures for inserting implants into the eye.

Background of the Invention

Artificial intraocular lenses are widely used to replace the human crystalline lens of the eye. The human crystalline lens is a living transparent structure composed primarily of protein having a thickness of about five millimeters and a diameter of about nine millimeters. The lens is suspended behind the iris by zonula fibers that connect the lens to the ciliary body. A lens capsule surrounds the lens; the front portion of the capsule generally referred to as the anterior capsule and the back portion generally referred to as the posterior capsule.

The term "cataract" refers to the opacity of the lens of the eye. There are a variety of types of cataracts and for most cataracts, surgical intervention is required to remove and replace the lens with an artificial intraocular lens.

The transparency of the lens depends on the physiochemical state of the lens proteins. These proteins, like the proteins of other organs, are sensitive to changes in the properties of their surrounding fluid. Changes in the concentration of dissolved salts, in the osmotic pressure, in the pH or in the enzyme activity of the surrounding fluid can alter the properties of the lens proteins. Also, like other organs, changes to the proteins of the lens occur with age. A common type of cataract that occurs in elderly people is known as a senile cataract. This type of cataract has no known etiology and none of the forms of cataract produced experimentally to date closely resemble the senile cataract.

Artificial intraocular lenses generally comprise an optical region and a support, or haptic, to facilitate positioning and centering of the intraocular lens within the eye. Intraocular lenses have been made from a number of different materials. For example, hard lenses have been prepared from polymethylmethacrylate (PMMA) and optical glass while flexible lenses have been prepared from silicone, polyHEMA (polyhydroxyethylmethymethacrylate), acrylics, collagen, and combinations thereof. Flexible lenses have the advantage that they can be folded or otherwise deformed prior to implantation to reduce the overall size of the lens during the artificial lens implantation procedure.

There are a number of procedures and devices that have been developed for the removal of the natural lens followed by the insertion of an artificial lens. The extraction procedure can generally be categorized as intracapsular (i.e., where the lens is removed together with the lens capsule) or extracapsular (such as where a portion of the anterior capsule is circularly removed (capsulorhexis) and the posterior capsule is left intact).

Presently, phacoemulsification is a widely used method for the removal of diseased or damaged natural lens tissue. The phacoemulsification process generally employs a small incision typically of about 2 millimeters (mm) to about 4 mm in length (but potentially as small as 1 mm) through the cornea and a probe is used to ultrasonically break apart and remove the crystalline lens through the capsulorhexis.

There are a number of intraocular lens injectors that have been described in the literature to position a deformable artificial intraocular lens in the eye. These injectors use an incision of about 2 mm to about 4 mm, the incision size most frequently used in most phacoemulsification procedures. A larger (about 4 mm to about 5 mm) capsulorhexis incision, also used in phacoemulsification procedures, is used to position the lens without requiring elongation of the incision during the injection process.

U.S. Pat. No. 4,681,102 to Bartell discloses one type of device to implant an intraocular lens through a small incision. The injector comprises a load chamber that is used to fold a soft intraocular lens into a shape having a smaller cross-sectional area than the original unfolded cross-sectional dimension of the

lens. The load chamber comprises two hinged members that together define a generally cylindrical lumen. Each of the two members includes a flange that extends non-parallel to cylindrical members at a point of connection and permits manipulation of the cylindrical members from a first open position to a second closed position. The intraocular lens is inserted into the load chamber when the two members are in an open position. The flanges are advanced towards each other causing the two members to form the generally cylindrical chamber. As the two members advance towards each other, the intraocular lens that is inserted in the chamber is compressed to conform to the generally cylindrical shape of the members in the closed position. This device and those devices that include a rigid chamber for deforming the lens can damage the lens during the deformation process if the lens is not accurately and carefully positioned in the chamber.

A number of patents use a pushrod (also described in these patents as a pusher or piston-type device) to apply a force directly on a lens and to push the deformed lens from the device into the eye. For example, the loading chamber of Bartell (*supra*) is placed into a rigid injector portion fitted with a pushrod. The pushrod pushes the intraocular lens through a generally circular lumen of the loading chamber and into an injector nozzle. The pushing action of the pushrod can further damage the lens material and haptics before the lens is positioned in the eye.

U.S. Pat. Nos. 4,702,244 and 4,573,998 to Mazzocco discloses a pushrod type of device that functions similar to a plunger of a syringe to provide a hydraulic force on a lens. The device includes a chamber for containing the intraocular lens in an unstressed state and for orienting the lens in a prescribed orientation to facilitate lens placement within the eye. The plunger is used to exert a direct force on the lens or a direct force on liquid surrounding the lens, sufficient to deform the lens such that the optical zone is deformed to a substantially smaller cross-sectional diameter than the optical zone in an unstressed state. The device includes a means to expel the lens from the device for placement in the eye. The surgical device disclosed by Mazzocco requires the use of a direct force such as a hydraulic force or a pneumatic force to move the lens from its unstressed stated into a deformed position. In the embodiment

that compresses the lens from an unstressed state to a stressed state, the lens is propelled toward a small opening at the end of a holding tube. As the lens approaches the opening it is folded back against itself and compressed to fit through the opening. The orientation of the lens in the device is not uniform, nor would deformation be consistent with each injection. Moreover, the hydraulic force would likely be quite high and this pressure is likely not practical for use in the internal aspects of the eye.

U.S. Pat. No. 5,468,246 to Blake discloses another type of intraocular lens injector that compresses the diameter of the intraocular lens by rolling the lens into a tight cylindrical tube that can be inserted into the eye through a small incision of about 2 millimeters to about 4 millimeters. This device also uses a pushrod-type device to apply a direct force to move the lens from the injector device into the eye.

U.S. Pat. Nos 5,562,676 to Brady, 5,275,604 to Rheinish, 5,474,562 to Orchowski, 4,919,150 to Stoy, 5,123,905 to Kelman and 5,616,148 to Eagles use an injector with a tapered or conical loading chamber to guide and fold the lens into a rigid lumen. These patents also use a pushrod to inject the lens from the lumen into the eye. A problem with these injectors is that the internally positioned pushrod is in direct contact with the lens assembly. This direct contact can result in distortion, bending or breakage of a trailing haptic. In addition, compressive forces on soft or fragile lens materials can tear the lens or destroy a haptic. In addition, during compression, the pushrod can catch or wedge a portion of the lens between the rigid lumen of the device and the pushrod mechanism.

There remains a need for a device for introducing a flexible implant, particularly fragile foldable lenses into the body without damaging that implant. In particular, there is a need for a device to implant a foldable intraocular lens into an eye without damaging the lens or the haptics during the implantation process.

SUMMARY OF THE INVENTION

This invention relates to a device and for methods for inserting an implant in a portion of the body. In a preferred embodiment, the device is useful for implanting a lens into an eye. The device employs an off-axis force relative to the plane of movement of the lens during implantation. Preferably the off-axis force is applied to compress or squeeze a compressible sleeve at a position behind the implant to advance the implant from the sleeve into the body.

In one aspect of this device the invention relates to a device for positioning a flexible implant in a portion of the body comprising a compressible sleeve to contain an implant and means for squeezing the compressible sleeve to advance the implant from the sleeve. Preferably the flexible implant is a lens, including an intraocular lens that can be a single-piece lens or a multi-piece lens. In another aspect, the implant is a subcutaneous implant. The means for squeezing the compressible sleeve preferably includes at least one blade, and preferably two blades. Alternatively, the means for squeezing can include a squeezing ring or a squeezing tool, including those described in this invention.

In another aspect of this device, the device can include a housing for the sleeve. In one variation, the housing can include a hand-piece, a pusher element or a combination thereof. In a preferred embodiment, the means for squeezing the compressible sleeve is affixed to the pusher element.

Preferably the sleeve is prepared from a flexible polymeric material and a preferred embodiment of the sleeve is a sleeve including a first opening, a second opening and a tapered portion, wherein the first opening is larger than the second opening. In one embodiment, sleeve further comprises at least one pleat or a plurality of pleats.

In another embodiment of this invention, a device for introducing an implant into a portion of the body is disclosed where the device comprises a hand-piece having a lumen, means for stabilizing a compressible sleeve in the lumen and a pusher element wherein the pusher element comprises at least one blade. In a preferred embodiment, the means for stabilizing a compressible sleeve is a collet. In another embodiment, the means for stabilizing a

compressible sleeve is a sleeve holder and preferably the sleeve holder is a groove or at least one post.

In this embodiment, preferably, the blade contacts the sleeve when the sleeve is positioned in the lumen. In one aspect of this device, the device further comprises a compressible sleeve and can also further comprise an implant. In one embodiment, the implant is a lens, preferably an intraocular lens, an implant to treat glaucoma, a contact lens, or an implantable contact lens.

The compressible sleeve preferably comprises a first end and a second end, wherein the first end is affixed to the housing. In one aspect of this embodiment, the implant is supplied in the compressible sleeve. The second end of the sleeve can include an opening extending from the lumen of the housing and the second end of the sleeve can include a cap. In one embodiment where the device comprises a compressible sleeve, the second end of the compressible sleeve is flared or in another, the second end of the sleeve is tapered. In another embodiment of this device, the second end is tapered from a first cross-section to an opening having a second cross-section, wherein the opening is sized to receive an implant.

In an embodiment of this device where the means for stabilizing a compressible sleeve is a collet, preferably the collet comprises a proximal end, a distal end and a lumen extending between the proximal end and the distal end. In one embodiment with a collet, the collet further comprises at least one slit extending from the proximal end of the collet and preferably the distal end of the collet has a cross-sectional configuration selected from the group consisting of a scrolled pattern, a circle, a rhombus and a winged circle. Also preferably, the collet is tapered in cross-sectional dimension from the proximal end of the collet to the distal end of the collet. In addition, the surface of the lumen of the collet can include external folding guides.

This invention also relates to compressible sleeves. In one embodiment of a compressible sleeve, the compressible sleeve comprises a flexible polymeric material, the sleeve further comprising a first opening and a second opening, and an implant wherein the size of the first opening is greater than the size of the second opening. In a preferred embodiment, the implant is a lens, preferably an

intraocular lens, or a glaucoma implant. Preferably, the implant is prepared from a soft polymeric or gelatinous material. In one embodiment of this invention, the sleeve further includes at least one cap or seal and can also include a viscoelastic solution or a buffered solution. The sleeve can be prepared as a single, completely integral piece or as a multi-piece lens, prepared, for example in two pieces.

In another embodiment of a compressible sleeve, the sleeve comprises a flexible polymeric material, the sleeve further comprising a first opening, a second opening, and a tapered portion, wherein the size of the first opening is greater than the size of the second opening and wherein at least the tapered portion has a cross-sectional configuration selected from the group consisting of one pleat, a plurality of pleats, a V-shape, an oval, a circle, and an envelope. In one version of this sleeve, the sleeve further comprising an implant. Again, the sleeve can be prepared as a single, completely integral piece or as a multi-piece lens, prepared, for example in two pieces.

In another embodiment, the invention relates to a flexible, elongated, compressible sleeve housing a foldable lens.

The invention also relates to a device comprising a pushing mechanism, a squeezing means to advance an implant in the device, a flexible, compressible sleeve and means for immobilizing the sleeve in the device.

The invention further relates to a kit comprising a device comprising a pushing mechanism, a squeezing means to advance an implant in the device and means for immobilizing the sleeve in the device, and a flexible, compressible sleeve. The kit can further include a squeezing tool and/or an implant. Preferably, the implant is a lens.

In yet another embodiment, the invention relates to a device for introducing an implant in the body comprising a housing comprising a first end and a second end, with an opening positioned at the second end, a compressible sleeve, and a pushing mechanism affixed to at least one squeezing blade positioned within the housing wherein the squeezing blade contacts the compressible sleeve. In one aspect of this device, the pushing mechanism is a multi-step pushing mechanism. In another aspect of this device, the sleeve is

affixed to a sleeve holder positioned in the housing. The device can also include an implant positioned within the sleeve. In one aspect of this embodiment, the housing further comprises a tapered portion at the second end and can include external folding guides within the housing. In another preferred aspect of this embodiment, the sleeve comprises a cross-sectional configuration selected from the group consisting of one pleat, a plurality of pleats, a V-shape, an oval, a circle, and an envelope.

In another embodiment of this device, the sleeve comprises a first end affixed to the sleeve holder and a second end, wherein the second end is tapered from a first cross-section to an opening having a second cross-section, wherein the opening is sized to receive an implant. In this embodiment, the sleeve can extend from the opening in the housing and preferably the end is capped or sealed. The device can further include a sleeve positioned in the housing using a clamp or screw. In one embodiment, device comprises a collet and the collet preferably comprises a proximal end, a distal end and a lumen extending between the proximal end and the distal end. The collet can further comprise at least one slit extending from the proximal end of the collet and preferably, the distal end of the collet has a cross-sectional configuration selected from the group consisting of a scrolled pattern, a circle, a rhombus and a winged circle. Also preferably, the collet is tapered in cross-sectional dimension from the proximal end of the collet to the distal end of the collet. The surface of the lumen of the collet can comprise external folding guides and preferably at least a portion of the surface of the lumen of the collet comprises a rectangular cross section.

In another preferred aspect, the housing can comprise a slot to receive the sleeve. And preferably the sleeve is immobilized in the housing using a clamp or screw.

This invention also relates to methods for implanting or inserting an implant into a portion of the body. In one method for implanting an implant in a portion of the body, the method comprises the steps of providing a housing comprising a first end and a second end, with an opening positioned at the second end and a pushing element affixed to at least one squeezing blade

positioned within the housing, loading an implant into a compressible sleeve and introducing the sleeve into the housing wherein the blade contacts the sleeve, and moving the pushing element to advance the implant in the sleeve toward the opening.

In another method for introducing an implant into a compressible sleeve, the method comprises the steps of providing a sleeve comprising a first opening, a second opening, and a tapered portion positioned between the first opening and the second opening, introducing an implant into the first opening of the sleeve, and squeezing the implant past the tapered portion of the sleeve.

In yet another method for inserting an implant, the method comprises the steps of positioning an implant into a compressible, flexible sleeve, and squeezing at least a portion of the sleeve to advance the implant through at least a portion of the sleeve. In one embodiment, the squeezing step uses a squeezing tool, in another embodiment, the squeezing step uses at least one squeezing blade, and in another embodiment, the squeezing step uses a squeezing ring.

The invention also relates to a device for positioning an implant within a body, the device comprising a sleeve having a proximal and a distal end, an implant located within the sleeve, means for compressing a portion of the sleeve between the proximal end of the sleeve and the location of the implant within the sleeve, means for advancing the compressed portion of the sleeve towards the distal end of the sleeve, whereby the implant is urged towards the distal end of the sleeve.

The invention also relates to a method for positioning an implant within a body comprising the steps of providing an implant located within a sleeve, the sleeve having a proximal end and a distal end, compressing a portion of the sleeve between the proximal end and the implant located within the sleeve, and advancing the compressed portion of the sleeve towards the distal end of the sleeve, whereby the implant is urged towards the distal end of the sleeve. In one embodiment of this method, the method further comprises the step of positioning the distal end of the sleeve within a body.

The invention also relates to a method for delivering an implant within a body comprising the steps of providing a sleeve having a proximal end and a

distal end introducing an implant into the proximal end of the sleeve, compressing a portion of the sleeve between the proximal end and the implant located within the sleeve, and advancing the compressed portion of the sleeve towards the distal end of the sleeve, whereby the implant is urged towards the distal end of the sleeve.

In another aspect of this invention, the invention relates to a flexible compressible sleeve comprising a first opening and a second opening with a lumen extending through the sleeve, wherein the size of the first opening is greater than the size of the second opening and wherein the thickness of a wall of the first opening is thinner than the thickness of a wall of the second opening. In one embodiment, the sleeve has a length of about 10 mm to about 50 mm. In another embodiment the width of the sleeve is about 1.5 mm to about 4 mm at the second opening. Preferably, the thickness of a wall of the first opening is about 0.01 mm to about 0.1 mm. and the thickness of a wall of the second opening is about 1.5 mm to about 3.5 mm. Still more preferably, the sleeve is distendable.

In another aspect of this invention, the invention relates to a flexible, compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve, wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening.

The invention also relates to a system for loading an implant comprising: a flexible, compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve, wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening; and a sleeve holder prepared from a substantially rigid material and comprising a lumen extending therethrough, wherein the lumen comprises a first opening and a second opening and wherein the first opening is larger than the second opening and wherein the lumen is adapted to substantially conform to the shape of the sleeve.

In a further aspect of this invention, the invention relates to a sleeve supporting device comprising a substantially rigid body comprising a lumen

extending therethrough, wherein the lumen comprises a first opening and a second opening and wherein the first opening is larger than the second opening and wherein the lumen is adapted to substantially conform to the shape of a sleeve. Preferably the width of the first opening is from about 4.5 mm to about 10 mm and the width of the second opening is from about 1.5 mm to about 4 mm.

The invention relates to a kit comprising: a flexible, compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve, wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening; and an implant. Optionally, the kit can further comprise a sleeve holder prepared from a substantially rigid material and comprising a lumen extending therethrough, wherein the lumen comprises a first opening and a second opening and wherein the first opening is larger than the second opening and wherein the lumen is adapted to substantially conform to the shape of the sleeve. In one embodiment, the implant is a flexible lens.

In another aspect of the invention, the invention relates to a device for introducing an implant into the body comprising: a flexible compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve, wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening; and a hand-piece capable of mobilizing the implant and immobilizing the sleeve. In one embodiment, the implant is a lens and preferably an intraocular lens. In one embodiment, the hand-piece comprises at least one blade to mobilize the implant by squeezing the sleeve and in another the hand-piece comprises a pushrod positioned within the sleeve to mobilize the implant. In a preferred embodiment, the hand-piece further comprises a pressure fit element to immobilize the sleeve in the hand-piece and preferred pressure fit elements include a collet or a screw

The invention also relates to device for introducing a flexible implant into a portion of the body comprising: a compressible, flexible sleeve comprising a flexible polymeric material and a lumen extending through the sleeve; an

implant positioned in the sleeve; and a hand-piece wherein the hand-piece further comprises a push-rod that extends into the sleeve. Preferably the sleeve has a first opening and a second opening and wherein the width of the first opening is larger than the width of the second opening and preferably the push rod has a rounded tip.

In another aspect of this invention, a method is disclosed for preparing a flexible, non-opaque sleeve comprising the steps of: positioning a flexible, compressible, deformable tubing in a press wherein the press comprises at least two compressive surfaces; applying a compressive force to the tubing to permanently distend at least a portion of the tubing and to form a distended portion of the tubing and a non-distended portion of the tubing; cutting the tubing in the distended portion and cutting the tubing in the non-distended portion to form a sleeve. In a preferred embodiment, the tubing is a polymeric tubing and in a preferred embodiment the tubing is PTFE or ETFE. In one embodiment the press is a cold press and in another embodiment, the press further comprises heat. In a preferred embodiment the thickness of the wall of the distended tubing is at less than two-thirds of the thickness of the tubing before applying the compressive force.

The invention also relates to an intraocular lens insertor, the improvement comprising the use of a flexible, compressible immobilized sleeve housing an intraocular lens wherein the lens is positioned in the sleeve before the sleeve is immobilized in the insertor.

In another embodiment the invention is a device for introducing an implant into the body comprising; a flexible compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve, wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening; an implant; and a hand-piece comprising a pushrod to fit within the flexible sleeve and means for advancing the pushrod to mobilize the implant in the device. Preferably the sleeve is tapered from the first opening to the second opening and preferably the thickness of a wall of the first opening of the sleeve is less than two-thirds of the thickness of a wall of the second opening of the

sleeve. In one embodiment, the implant is a lens and in a preferred lens embodiment, the lens is an intraocular lens.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of a preferred lens insertor of the present invention. Figure 1a is a perspective view of a collet and Figure 1b is a cross-section through the collet at G-G as illustrated in Figure 1.

FIG. 2 illustrates a preferred sleeve embodiment and a squeezing tool according to this invention.

FIG. 3 illustrates a series of cross-sectional configurations of at least the tapered portion of the sleeve of this invention. Figure 3a illustrates a circular cross-section; Figure 3b, an elliptical cross-section; Figure 3c, a flattened cross-section; Figure 3d, an enveloped cross-section; Figure 3e, a pleated cross-section; Figure 3f, a plurality of pleats in cross-section; Figure 3g, a "V" shaped cross-section.

FIG. 4 (a) through 4(e) are cross-sectional views of the distal portion of a collet from the device of Figure 1. Figure 4a illustrates a round configuration; Figure 4b, a rhomboid configuration; Figure 4c, a winged circular configuration; Figure 4d, an expanded winged circular configuration; Figure 4e, another embodiment of an expanded winged circular configuration; and Figure 4f, a scrolled configuration.

FIG. 5a is a cross-sectional view of a multi-piece sleeve according to this invention. Figure 5b illustrates a multi-piece sleeve following separation of the sleeve.

FIG. 6 is a cross-sectional view of an assembled insertor device according to Figure 1.

FIG. 7 is a cross-sectional view of the assembled insertor device of Figure 6 rotated 90°.

FIG. 8 is a perspective view of the distal portion of an assembled insertor device according to this invention.

FIG. 9 is a cross-sectional view of a lens preassembled in a sleeve.

FIG. 10a is a cross-section of a front-loading device according to this invention with a front-loading sleeve. Figure 10b is a view of the front loading device with a squeezing tool.

FIG. 11 is an illustration of a preassembled insertor according to the present invention illustrating a multi-step pushing mechanism. Figure 11a illustrates the preassembled insertor. Figure 11b illustrates a first step in the pushing mechanism and Figure 11c illustrates a second step in the pushing mechanism.

FIG. 12 is another embodiment of a lens insertor of this invention illustrating external bending guides. Figure 12b provides a cross-section through the insertor to illustrate the external bending guides.

FIG. 13 is another embodiment of an insertor according to this invention.

FIG. 14a is a cross-sectional view of the eye with a device according to this invention inserting a foldable intraocular lens. Figure 14b is a cross-sectional view of an eye receiving an implantable contact lens using a device of this invention.

FIG. 15 is an enlarged partial cross-sectional view of the interface between a preferred means for compressing a sleeve in accordance with the present invention.

FIG. 16a is a perspective view of a sleeve with an intraocular lens for insertion into a collet. FIG. 16b is a view of an assembled sleeve and collet. FIG. 16c illustrates assembly of a ring clamp onto the collet and FIG. 16d illustrates an assembled sleeve in a collet positioned with a ring clamp.

FIG. 17a is a perspective view of an assembled sleeve, collet and ring clamp positioned onto a hand-piece with blades. FIG. 17b is a perspective view of the assembled device of FIG. 17a. FIG. 17c is a cross-section through lines D-D illustrating the position of blades around the sleeve within the lumen of the collet.

FIG. 18a is a perspective view of an assembled sleeve, collet and ring clamp positioned onto a hand-piece with a push-rod. FIG. 18b is a perspective view of the assembled device of FIG. 18a. FIG. 18c is a cross-section through

lines E-E illustrating the position of the push-rod in the sleeve within the lumen of the collet.

FIG. 19 is a perspective view of a preferred sleeve holder of this invention.

FIG. 20 illustrates a preferred method of this invention for preparing a sleeve.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a novel device for the introduction of a variety of implantable devices, preferably lenses, such as an intraocular lens, into the eye. The invention also relates to the use of a flexible and distendable sleeve to house a flexible implant during introduction of the implant into the body. In contrast to other implantation devices currently available, one embodiment of this invention applies off-axis an external squeezing force on a flexible, distendable sleeve containing an implant to gently urge the implant through the sleeve, from the device and into the body. Other devices for the implantation of intraocular lenses currently apply a direct force such as through a compressive pushrod, also referred to as a pusher or piston, that directly contacts the lens to inject the lens into the eye. In a preferred application of the present invention, the device is useful for the introduction of a lens into the eye and in particular, for the introduction of an intraocular lens through an incision in the ocular tissue, such as the incisions employed using a phacoemulsification cataract removal procedure.

The devices of this invention are insertion devices. That is, the term "insertor" is used herein to refer to a device that places an implant into a passageway, cavity or tissue of the body. In one embodiment of this invention, the insertors of this invention use an off-axis or indirect force to advance the implant into the body.

The devices of this invention are useful for inserting a variety of items in the eye. For example, in a preferred device, the device is used to insert an intraocular lens into the eye. Modifications of the device permit the design of a variety of devices suited for insertion of a variety of lenses or implants into the

eye including, but not limited to, a posterior and anterior intraocular lens, a corneal inlay lens inserted into the cornea of the eye, either as an inlay or as a corneal refractive implantable contact lens (ICL), a scleral buckle implant, to introduce a contact lens onto the eye, to introduce an artificial duct or implant material including tubing, and the like into the eye to shunt fluid from the anterior chamber of the eye such as for glaucoma surgery. The devices of this invention can be used to position an implant elsewhere in the body. For example, to introduce subcutaneous or intramuscular implants, including sustained drug release devices, or as catheter-like devices, and the like. While the present invention is described by way of its ability to introduce an intraocular lens or other lenses into an eye, those of ordinary skill in the art will recognize that a variety of implantable items can be introduced into a variety of positions in the body through devices as described in this invention.

The term "proximal" is used herein to refer to that portion of the device or element of the device that is closest to the physicians finger that is being used to activate the pusher element of the devices of this invention. The term "distal" is used herein to refer to that portion of the device or element of the device that is farthest from the physician's finger that is being used to activate the pusher element of the devices of this invention.

The term "squeezing" is used herein to refer to a compressive off-axis force applied behind an object to mobilize the object ahead of the off-axis force along a defined course. The compressible force includes a component transverse to the longitudinal axis of the device, where the longitudinal axis is defined by the direction of movement of the implant being inserted.

The term "soft implant" is used herein to refer to a malleable, ductile, compressible elastic, rubbery or gelatinous substance having a reading on an A durometer of generally about 20 A to about 70A, but could be as low as 5 A for a hydrophillic contact lens or about 90 A for a flexible acrylic material. Durometer instruments are available from Pacific Transducer Corp., Los Angeles, CA.

The term "flexible and compressible" sleeve refers to sleeves prepared from a variety of flexible materials, including flexible polymeric materials, such

as those that can be generally measured on a D scale or an A scale, and preferably materials having a D durometer reading from about 40 D to about 80 D. Other hardness scales can also be used. In general, durometer testers and their methods of use are described in ASTM D-2240. The "A" scale can be used, for example, to measure the flexibility or relative hardness of synthetic rubbers, neoprene, silicones, felt, and the like. The "B" scale can be used to measure the flexibility or alternatively the relative hardness of a variety of rubbers and elastomers. The "C" scale is used to measure medium hard rubbers and plastics. The "D" scale is used to measure a variety of plastics, plexiglass, polystyrene, vinyls, and the like. The "OO" scale can be used to measure the hardness of materials such as sponges, rubber or soft rubber. Those of ordinary skill in the art will recognize that the materials need be readily compressible by the blades of the devices of this invention and therefore, a variety of materials used to construct objects to be inserted as an implant are considered "flexible and compressible" and preferably malleable for purposes of this disclosure, particularly in view of exemplary sleeve materials supplied later in this disclosure.

The term "pleat" as used in this invention refers to one or more folds or creases present in all or a portion, preferably at least the tapered portion, of a sleeve of this invention.

Figure 1is a preferred embodiment of the present invention for inserting a lens into the eye of a patient. The exploded view of insertor 10 provides a hand-piece 12, including a pusher element 14 capable of engaging at least one push-blade 16, a collet 18 capable of receiving a compressible sleeve 20 and a ring clamp 22 to secure the collet 18 to hand-piece 12.

Sleeve 20 is prepared from a compressible, flexible, deformable and smooth material, preferably a flexible polymeric material such as ethylene tetrafluoroethylene (ETFE, Zeus Corp. Orangeburg. S.C.), but other materials can be used, including, but not limited to: other tetrafluoroethylenes (e.g., polytetrafluoroethylene (PTFE), fluorinated ethylenepropylene, perfluoro-alkoxyfluorocarbons, flexible vinyls (e.g., polyvinyl chloride or polyvinylide fluoride), polyimide, polyamide, polyester, silicones, polyolefin materials, non-

opaque TEFLON, polyvinyl chloride with a hardness range of about 35D to about 80D, etc. Preferred materials are sufficiently non-opaque that an implant can be seen in the sleeve when positioned therein. Sleeve 20 is preferably formed from a flexible, deformable and compressible tubing (e.g., ETFE or PTFE tubing) that is preferably malleable and capable of being pressed or distended. Alternatively, the sleeve can be injection molded. The sleeve 20 can be coated on its interior or exterior surfaces with a variety of friction reducing materials to ease the passage of a lens through the length of the sleeve 20. The coatings can, for example, reduce friction on the lens by the sleeve. Preferred coating materials include, but are not limited to, silicones, such as HYDRO-SIL (TUA Systems, Sarasota, FL), ion -exchange hydrophilic treatments such as HYDRO-SILK or other coatings including, but not limited to, heparin, PARYLENE (Nova Tran Corp., Clear Lake, WI), or NOVA TRAN (Nova Tran Corp), etc.

Referring now to Figure 2, sleeve 20 preferably includes a first opening 24 capable of receiving an intraocular lens. In one embodiment, first opening 24 (proximal portion of sleeve) has a width that is sufficient to receive an unfolded or substantially unfolded lens; however the first opening 24 can be small enough to require some deformation of the lens. Typically for intraocular lens implantation, first opening 24 is preferably at least about 1.5 millimeters (mm) in width and preferably less than about 10 mm in width and preferably for an intraocular lens insertor, greater than about 3 mm and less than about 9 mm in width. The walls of the material used to prepare sleeve 20 can be a variety of thicknesses provided that the sleeve 20 remains readily compressible by, for example, blades 16, maintains its integrity during use and is sufficiently deformable to permit positioning of an intraocular lens within the sleeve.

The first opening 24 of the sleeve can have any of a variety of configurations including, but not limited to, straight edges, such as provided in FIG. 2, chamfered edges, curved edges, either concave or convex curves relative to the tip of the sleeve. Alternatively, the first opening 24 of the sleeve can be angled.

Sleeve 20 also includes a second opening 26 in the tubular portion of the sleeve and the width of sleeve 20 preferably decreases over at least a portion of the sleeve from first opening 24 to second opening 26 to provide a tapered portion 28 to sleeve 20. In a preferred embodiment, the taper of sleeve 20 preferably reduces the dimension of the sleeve from the first opening 24 to the second opening 26 within one-half of the length of the sleeve. The tapered portion 28 reduces the width of the sleeve toward the distal portion of the sleeve. For the intraocular lens embodiment, second opening 26 is at least about 1 mm in diameter and preferably less than about 4 mm in diameter with preferred dimensions for an intraocular lens insertor of between about 2 mm to about 2.5 mm for soft flexible lenses and as much as 4 mm for less flexible lenses such as acrylic lenses.

Preferably, the length of sleeve 20 is preferably at least about 1cm and more preferably at least about 2 cm, for the intraocular lens embodiment, the sleeve is at least about 5 cm and typically, the sleeve 20 will be less than about 10 cm in length. In a preferred embodiment of an intraocular lens insertor, the length of sleeve 20 is preferably greater than about 2.5 cm and less than about 3 cm. For the front loading device, discussed below, the sleeve can be about 5 cm. Although longer or shorter sleeve lengths can be adapted to longer or shorter devices. Second opening 26 is preferably beveled, from about 16 ° to about 75° much like the tip of a needle to ease insertion of the implant into the eye, although a variety of configurations to second opening 26 are possible. The second opening 26 of sleeve 20 can take on a variety of other shapes and in one embodiment the second opening 26 is ellipsoid or circular in cross-section. Optionally, second opening 26 of sleeve 20 can be tapered or can be flared.

In a preferred sleeve embodiment, illustrated in Figure 3, the cross-section of the sleeve 20 can have a variety of configurations. In a preferred embodiment, the tapered portion 28 of sleeve 20 can have any one of the configurations provided in Figure 3. Figure 3a illustrates a circular cross-section 30; Figure 3b, an elliptical cross-section 32; Figure 3c, a flattened cross-section 36; Figure 3d, an enveloped cross-section 34; Figure 3e, a pleated cross-section 38; Figure 3f, a plurality of pleats in cross-section 40; Figure 3g a "V" shaped

configuration in cross-section, or a combination thereof. Those skilled in the art will appreciate that there are a number of other cross-sectional configurations that are possible.

In one embodiment, the tapered portion 28 of sleeve 20 is pleated 38 (see Figure 2) for at least a portion of its length and preferably the tapered portion 28 of sleeve 20 is pleated while the distal portion of sleeve 20 is generally circular in cross-section but could be ovoid or flattened. The cross-sectional configurations of the sleeve 20 can serve as guides to promote folding of the implant, such as a lens in a sleeve. In addition, the shape of the sleeve 20 at the first opening 24 of the sleeve can vary and could be flattened, ellipsoid, ovoid, enveloped, pleated, or the like. Moreover, the cross-sectional configuration of sleeve 20 can vary from first opening 24 through tapered portion 28 to second opening 26. For example, the cross-section at first opening 24 can be ovoid, while the tapered portion is pleated and the portion of the sleeve adjacent to second opening 26 can be circular in cross-section. Pleats are not necessary and in the embodiments using a sleeve holder (*infra*), pleats are optional.

Sleeve 20 of Figure 2 is illustrated as a single piece sleeve, that is a completely integral object. However, it is also contemplated that the sleeve 20 can be constructed from two or more pieces to form a multi-piece sleeve. Figures 5a and 5b illustrate a preferred embodiment of a multi-piece sleeve. The sleeve 21 comprises a first opening 25 at the proximal portion of the sleeve, a second opening 27, with a beveled tip, at the distal portion of the sleeve and a tapered portion 29 with the connection 31 between the two pieces preferably positioned just distal to the tapered portion 29. The sleeve pieces can be used as an intact sleeve or the portion of the sleeve including the first opening 25 can be discarded while that portion of the sleeve including the second opening 27 and the lens 50 can be used separately. Alternatively, a lens in a uniformly tubular sleeve can also be employed, such as that portion of the sleeve with opening 27 illustrated in Figure 5b. The multi-piece lens can be used, for example, with the front loading device of Figure 9, as described below.

In one embodiment, both proximal and distal portions of the sleeve are prepared from ETFE, PTFE, or the like, and in another embodiment that part of

the sleeve including second opening 27 is prepared from ETFE or PTFE while that portion of the sleeve including first opening 25 can comprise an elastic portion such as a soft silicone, an elastomeric latex, or another flexible material. Alternatively, the multi-piece sleeve can be prepared from materials with different hardnesses. In one example, that portion of the sleeve including first opening 25 can be prepared from a flexible, deformable material while that part of the sleeve including second opening 27 can be more rigid. Where the sleeve 21 is provided as a multi-piece sleeve, preferably the portions of the sleeve are affixed to each other by any suitable method or material including, but not limited to, an epoxy bond, a heat bond, silicone adhesive, acrylic adhesive, welding (e.g., ultrasonic, laser, etc.).

The sleeves of this invention are compressible, deformable and preferably flexible and malleable. The sleeves protect the implant from damage and provide a cost effective delivery system for introducing an implant into the body. Preferred dimensions of the sleeve at the narrower end (the second opening or tubular portion of the sleeve) is preferably 1.5 mm to about 4.0 mm in diameter and the preferred length of the sleeve is from about 10 mm to about 50 mm depending on the particular application of the insertor apparatus. The thickness of the wall of the first opening is preferably about 0.01 mm to about 0.1 mm. The thickness of the wall of the second opening is about 1.5 mm to about 3.5 mm. Preferably, the tubular portion of the wall is constant from the second opening to the distal end of the tapered portion. This disclosure includes a number of variations that all employ the sleeves of this invention. Those of ordinary skill in the art will recognize that the sleeves of this invention can further be incorporated into a variety of implantation devices including, but not limited to, intraocular lens insertors and injectors.

The hand-piece, pusher element, collet and ring clamp can be prepared from a variety of durable, stiff materials such as hard plastics, including moldable plastics, acrylics, styrene, clear, opaque or non-opaque materials. Those with ordinary skill in the art will appreciate the advantages of a non-opaque collet, for example, that permits the continued viewing of the lens during insertion. Hand-piece 12 and other hand-pieces of this invention can further be

prepared from stainless steel, polysulfone, polycarbonates, nylons, acetals or other suitable materials with or without glass, carbon or graphite fillers. The pieces can be prepared from heat or irradiation-stable materials for reuse or prepared as a disposable for single-use applications.

The sleeves of this invention are preferably disposable, and as discussed further below, the sleeves can be supplied with or without an implant. Where the sleeves of this invention are reused, care is taken to monitor wear of the sleeve and preferably, the sleeves are treated for microbial contamination before reuse.

Referring again to Figure 1, the device 10 includes a collet 18 to engage sleeve 20 and maintain orientation of sleeve 20 in the device. Collet 18 is substantially hollow to form an internal lumen 47 (Figure 1b) and comprises a proximal end 42 and a distal portion 46. Collet 18 is preferably slightly tapered down its length and in a preferred embodiment, collet 18 includes at least two slits 43 (see Figure 1a) for immobilizing the sleeve in the device and a notched portion 49, or other means, for engaging hand-piece 12 and preventing rotation of hand-piece12 relative to collet 18 during use. Those of ordinary skill in the art will recognize that there are a variety of modifications to the collet, hand-piece or ring-clamp that could be used to immobilize the sleeve of this invention and that, for purposes of this invention, an immobilized sleeve is an important and preferred aspect of this invention.

In a preferred embodiment, the internal lumen 47 of the collet 18 tapers toward the distal portion 46 of collet 18 to guide blades 16 toward the implant and to permit the blades to track smoothly as they advance the implant toward second opening 26 of sleeve 20. Figure 4 provides a number of cross-sectional views looking down the length of collet 18 from the distal portion 46 and including lumen 47. The distal portion 46 of collet 18 can take on any of a variety of cross-sectional configurations as illustrated in Figure 4. Figure 4a illustrates a round configuration; Figure 4b a rhomboid configuration; Figure 4c a winged circular configuration; Figure 4d an expanded winged circular configuration; Figure 4e an even more expanded winged circular configuration; and Figure 4f a scrolled configuration. Two edges of the rhombus (Figure 4b)

and the winged portions by cross-section (Figures 4c-4f) are available as guides for blades 16.

In addition to the modifications to the distal portion of the internal surface of collet 18 (Figure 4), the internal surfaces of the lumen formed in collet 18 can be modified in other ways. For example, lumen 47 can be modified as illustrated in cross-section G-G through collet 18 (see Figure 1b). This shape provides guidance and lateral stability to blades 16. Alternatively, modifications to the internal surfaces of the collet or where a collet is not used, the internal surface of the hand-piece can include guides such as those provided in Figure 11 or follow those of Rheinish et al. (U.S. Pat. No. 5,275,604). Further, the cross-sectional dimension of the internal lumen of the collet also preferably narrows from the proximal portion toward the distal portion of the collet 18 to permit blades 16 to track smoothly into contact with sleeve 20 when sleeve 20 is loaded into device 10. Importantly, the guides are positioned outside of the flexible sleeve and therefore do not contact the implant directly.

Hand-piece 12 (Figure 1) includes an elongate shaft preferably with a flange 45 at its proximal portion and threads 47 at its distal portion. Hand-piece 12 is preferably substantially hollow and is adapted to receive pusher 14. Distal portion 48 (see Figure 7) of hand-piece 12 is preferably adapted to receive notched portion 49 of collet 18. Distal portion 48 is also preferably threaded to receive ring clamp 22. Optionally hand-piece 12 also includes grips such as longitudinal grooves or roughened portions along its length to prevent sliding and unwanted rotational movement during use.

Pusher element 14 is preferably an extended rod that is adapted to fit within the hollow portion of hand-piece 12 and to mate in contour with hand-piece 12. Pusher element 14 preferably includes a broadened proximal portion 51 to facilitate movement of the pusher element 14 relative to hand-piece 12. Optionally, guides or ridges on the outer surface of pusher element 14 can be added to mate with matching receiving guides within the hollowed portion of hand-piece 12.

Preferably the device 10 is equipped with at least two blades 16 affixed to the distal portion of pusher element 14. The blades 16 can be prepared from a

variety of materials including, but not limited to, TEFLON, plastic, metal-reinforced plastic, stainless steel or other rigid materials. In a preferred embodiment, blades 16 are prepared from stainless steel wire, such as hard spring temper type 302 stainless steel wire rolled flat having a tensile strength of about 280,000 psi or type 17-7 precipitation hardening (PH) stainless steel drawn wire rolled flat and then heat treated to 240,000 psi in a vacuum or as much as 320,000 psi (Supreme Steel Treating Inc., El Monte, CA). However, steel wire greater than about 60,000 psi is also considered suitable for the blades of this invention. Those of ordinary skill in the art will recognize that the rigidity of the blade is a function of the type of material, the length of the blade and the thickness of the blade and that the selection of the material will also take into account the type of implant to be inserted into a portion of the body. Some plastics can be used, but plastic blades may be thicker than steel blades to provide sufficient rigidity to the blades.

In a preferred embodiment, using two blades for lens insertion, the blades 16 are at least 1 centimeter (cm) in length and preferably less than about 10 cm in length. For an intraocular lens embodiment, the blades are preferably greater than about 3.5 cm and preferably less than about 6 cm in length and more preferably less than about 4.5 cm in length. Also preferably, each blade is preferably at least about 1 mm in width and preferably less than about 10 mm in width. The length that the sleeve is selected to extend beyond collet 18 can vary and the length of blades 16 will vary with this length. Also preferably, each blade is at least about 0.25 mm in thickness and preferably less than about 1.5 mm in thickness. However, blades of as thin as 0.1 mm could function in a small, compact insertor.

In a preferred embodiment, the blades 16 are formed such that the tips of the blades bend slightly together. Those skilled in the art will recognize that the extent of the bend in the blades can be varied somewhat, particularly depending on the overall dimensions of the device. For example, the blades can be bent or curved in a slight arch or curved or bent slightly inward toward each other at one or more locations along the length of the blades. For example, blades can be curved inwardly from about 1 mm to about 10 mm relative to the plane formed

by the blade. Alternatively, the tip of the blade can be bent slightly such as from about 0.02 mm to about 0.2 mm relative to the plane formed by the blade. Blades 16 can be polished, as needed, to further reduce friction of the blades either in the hand-piece 12, the collet 18, or on sleeve 20. The blades can be affixed to the pusher element using adhesives, crimping, pinning or a variety of means known to those of ordinary skill in the art.

While the invention has been disclosed by way of the use of two blades, those of ordinary skill in the art will appreciate that a number of blades can be used. For example, it is possible to employ a single immobilized blade, prepared as a blade or as a portion of the collet, together with a single movable blade to apply an off-set force that squeezes the sleeve at a point proximal to the implant to advance the implant toward the distal portion of the sleeve. Alternatively, the device could employ three, four, or more blades positioned concentrically around the sleeve. Also alternatively, a single flat blade could move or alternatively be immobilized and two smaller blades could assist in advancing the implant through the device using the pusher 14. Further, rather than a blade, a solid ring or cylinder fitted over the sleeve can be used in place of one or more blades to advance an implant down a sleeve. The blades can also be fitted with guide grooves or ridges to assist in the axial tracking of the blades through the device.

In a preferred embodiment, illustrated in Figure 1, the blades are substantially flat, however; those of ordinary skill in the art will also appreciate that the blades can be wider and flattened to a greater degree than the blades illustrated in Figure 1. Alternatively, the blades can be cylindrical in shape, curved or ovoid. Again, the shape, width and thickness of the blade can be selected based on the type of implant, the dimensions of the implant, as well as the choice of blade material. Preferably, care is taken so that the edges of the blades are smooth and do not tear or substantially deform the sleeve during use.

Alternatively, the blades 16 can be configured similar to the blades of a tweezer. In yet another embodiment of this invention, blades 16 can also be encased in a layer of protective material, such as a layer of tubing, or an external, preferably transparent sheath, such as a separate flexible sheath or multiple lumen tubing, or a sleeve where at least the inner lumen containing the implant is

compressible and flexible and where the blades are encased each in their own covering within a second lumen that encompasses both the sleeve and the blades. Alternatively, the second lumen can be prepared from a rigid material to enclose the blades as they advance the implant, for example, such as where the blades do not extend beyond the distal portion of the hand piece.

The squeezing action of a blade or blades on a flexible and compressible sleeve containing one or more implants produces a controlled and deliberate movement of the implant through the sleeve along a predetermined axis of motion, defined by the sleeve, and at a controlled rate. The blades provide a means for compressing a sleeve and a means for advancing the compressed area of the sleeve toward the distal end of the sleeve. Those of ordinary skill in the art will recognize that other mechanisms employing these means can be incorporated into the devices of this invention. Those of ordinary skill in the art will recognize that forces on the flexible and compressible sleeve from the blade(s) and the frictional forces between the sleeve and the implant can be increased or decreased to maximize controlled movement of the implant through the device and into the body.

Device 10 also includes a ring clamp 22 adapted to fit over collet 18 and to secure onto hand-piece 12. Ring clamp 22 further compresses the sides of collet 18 to squeeze clamp the sleeve 20 within the collet 18 during use. Those of ordinary skill in the art will recognize that the ring clamp is not necessary and that device can be configured to secure the collet or its equivalent to the pusher element and to immobilize the sleeve in a variety of ways. Alternatively, the collet can be included as part of the hand-piece, such as for example, in the front-loading device discussed below.

Optionally a stopping mechanism, such as a stop bar or a key is positioned along the length of the hand-piece to mate with an extension on the pusher. A stop bar or key can be used to stop the blades and the pusher element from pulling out of the hand-piece or extending further than desired from the distal end of the collet. A key 214 is used in Figure 11.

To assemble device 10, a sleeve 20, preferably containing a lens 50 (see Figure 1) between second opening 26 and tapered portion 28 (i.e., preferably

substantially within the tubular portion of the sleeve) is introduced into lumen 47 of collet 18. Referring again to Figure 1, illustrating a preferred view of the proximal portion of collet 18 by cross-section. That portion of the sleeve 20 with second opening 26 is introduced into the length of collet 18 such that first opening 24 of sleeve 20 is positioned within the proximal portion of collet 18 and is positioned between slits 44 but preferably does not extend beyond slits 44 past the dimension of collet 18. Second opening 26 of sleeve 20 preferably extends beyond the distal portion of collet 18. Pusher element 14 with blades 16 is then introduced into hand-piece 12. Next, blades 16 are positioned on either side of sleeve 20 and moved toward the distal portion of the collet 18 preferably until resistance is felt on the blades due to the contact between blades 16 and that portion of sleeve 20 containing lens 50. Collet 18 is next positioned onto the distal portion of hand-piece 12, preferably mating notch 49 on collet 18 with a groove on hand-piece 12. Ring clamp 22 is positioned over sleeve 20 and around collet 18 and is securely engaged onto the distal portion of hand-piece 12. In use, pusher element 14 is pushed forward to move blades 16 down the length of sleeve 20 to gently urge lens 50 out of sleeve 20.

Figure 6 provides a cross-sectional view of the assembled device 10 in cross-section and Figure 7 provides a second cross-sectional view of the assembled device rotated 90° relative to Figure 6. Here, sleeve 20 contains a lens 50. The proximal portion containing first opening 24 of sleeve 20 is engaged within the proximal portion of collet 18 and collet 18 is positioned onto the distal end of hand-piece 12. Pusher element 14 is positioned within hand-piece 12, blades 16 are positioned on either side of sleeve 20 and ring clamp 22 is in place to secure sleeve 20 within collet 18 and to further secure collet 18 onto hand-piece 12. Movement of pusher element 14 relative to hand-piece 12 moves blades 16 toward the distal portion of the device and gently squeezes or urges lens 50 forward and out of sleeve 20.

Figure 8 is a perspective view of the distal portion of an assembled device 10. Here collet 18 is depicted with blades 16 extending from lumen 47 of collet 18 with lens 50 having been squeezed or urged from sleeve 20 by

movement of pusher element 14 and blades 16 distally down the length of sleeve 20.

In use, the physician can purchase the sleeve either alone or preassembled with an implant, such as a lens already positioned within the sleeve. Figure 9 illustrates a sleeve 60 with a lens 61, here an intraocular lens, positioned near first opening 62 at the proximal end of sleeve 60. A cap 63 or other sealing means, such as heat bonding, an adhesive, or the like is used to seal the proximal portion of sleeve 60 (that portion including first opening 64). In Figure 9, the second opening 64 is also capped with a second cap 65 or otherwise sealed, such as by heat bonding, an adhesive, or the like. The sleeve alone or the sleeve with the lens is provided in sterile form to the physician and where the implant is shipped in the sleeve, the sleeve preferably is filled, at least in part, with a suitable friction reducing material such as a lubricant or buffer, including a viscoelastic (i.e., an aqueous suspension of water and up to 10% of a composition including, for example, sodium hyaluronic acid, (i.e., HEALON), chondroitin sulfate, a cellulose such as HPMC (hydroxypropylmethyl cellulose), or a combination thereof) or a biocompatible liquid such as a variety of buffers known in the art, including phosphate buffers, saline, and the like.

Where the sleeve is supplied alone without an implant, the surgeon can optionally remove the caps or otherwise open the sleeve and introduce a suitable lubricant, by syringe or pipette, into one or both ends of sleeve 60 before introducing the implant into the sleeve. Where a syringe or pipette is used, care is preferably taken to maintain the integrity of the sleeve while the lubricant, buffer, or the like is added. Next, the implant, such as a lens, and preferably an intraocular lens, is placed inside the first opening. If a forceps is used, care is taken to gently position the lens just inside the first opening or alternatively positioned directly into the tapered portion and into at least part of the tubular portion of the sleeve. Optionally, the implant can be deformed, such as by using a forceps, prior or concurrently with the introduction of the implant into the sleeve. Where the implant is a lens, the implant can be folded slightly (i.e., less than 20% of the diameter of the lens) or substantially (i.e., greater than 50% of the diameter of the lens) before the lens is introduced into the sleeve. Preferably,

where the implant is a multi-piece intraocular lens with filament haptics, the lens is introduced into the sleeve with one haptic positioned in front of the lens and the second haptic trailing the lens. However, those skilled in the art will recognize that the lenses can be put into a sleeve in a variety of orientations without altering the scope of this invention. This invention is designed to accommodate a variety of implants, including a variety of lenses and a variety of intraocular lenses including, but not limited to, single piece intraocular lenses and three or more piece composite intraocular lenses that employ a plurality of haptic supports.

Referring again to Figure 2, preferably, once a lens 50 is positioned within the sleeve 20, a separate squeezing tool, such as tool 52 can be used to gently position the lens, at least in part, in the tapered portion 28 and preferably at least in part, past tapered portion 28 and into the distal portion or tubular portion of sleeve 20, such as illustrated in Figure 1. Squeezing tool 52 includes an elongate channel 54 into which first opening 24 of sleeve 20 is introduced. Once in place, tool 52 is advanced toward the distal portion of sleeve 20 with sleeve 20 passing in part, through channel 54 for a distance sufficient to urge lens 50 into position in sleeve 20 preferably past tapered portion 28. Sleeve 20 can then be assembled onto one of the devices of this invention. An alternative to the squeezing tool 52 is the use of the fingers to gently urge or otherwise nutate the implant through a sleeve.

The channel 54 of squeezing tool 52 can take on a variety of shapes. Preferably channel 54 is sufficiently long to accommodate the first opening 24 of sleeve 20. In a preferred embodiment, the channel is an elongate slit extending through squeezing tool 52 and preferably the channel is curved slightly. The channel 54 can be uniform in its height or the channel can vary in height or shape of the channel to facilitate varying dimensions of the implant. In a preferred embodiment, the channel 54 of squeezing tool 52 is shaped in an upward-curving or upward-angled manner, as illustrated in Figure 2, relative to the orientation of sleeve 20 when it is inserted in the squeezing tool 52 to promote the folding up of the lens in the sleeve such that when the lens is introduced into the eye, the edges of the lens open downward in the eye, much

like a flower unfolding, to minimize trauma to the eye as the lens opens from its folded position. The folding of the lens is further assisted by the cross-sectional configuration of the sleeve, such as by a pleat or a "V" shaped cross-section. The actual squeezing tool can take on a variety of geometries, for example in Figure 2 is rectangular in shape. Circular, square, or ovoid shaped squeezing tools could also be used and one of ordinary skill in the art can imagine a variety of shapes to the tool to facilitate its stabilization in the hand and to ease use. The squeezing tool 52 or gentle urging with fingers overcomes the damage to lenses that can be seen in devices that use a pushrod to directly contact the lens and advance the lens through these devices.

In a preferred embodiment, as illustrated in Figure 1, the implant is positioned in the sleeve and the sleeve is positioned through collet 18. Collet 18 is then positioned onto pusher element 14 and ring clamp 22 is used to immobilize the sleeve 20 on hand-piece 12. FIG. 16 illustrates the assembly of a sleeve 600 with an intraocular lens 602 into a collet 604. In FIG. 16a the sleeve is preferably positioned in the collet 604 with the second opening of the sleeve extending from the distal portion of the collet. The edges of the sleeve proximal to the first opening of the sleeve preferably extend at least to the edge of the slits 603 on either side of the collet. Once the sleeve 600 is assembled in the collet 604 a ring clamp 606 is positioned over the collet. Next, the ring clamp is secured to the hand piece thereby securing the collet to the hand-piece and exerting pressure on the collet to compress the slits 603 to immobilize the sleeve 600 on the device. As illustrated in FIG. 17a, a cross-section of the device through D-D of FIG. 17b, while assembling the ring clamp onto the hand-piece 608, blades 610 and 612 are positioned on either side of the sleeve within the lumen of the collet as illustrated in FIG. 17c. The assembled device of FIG. 17 is provided in FIG. 17b.

Following appropriate incisions, the device is positioned in the eye, preferably such that a beveled portion of second opening 26 of sleeve 20 (Figure 2) is positioned downward. The pusher element 14 is advanced slowly toward the distal portion of the device and the lens, positioned in the sleeve such that the

lens is folded upwards, is released into the eye with the folded edges opening downward, toward the eye as the lens is allowed to unfold.

Advantageously, the lens is oriented and folded consistently in sleeve 20 through the use of one or a combination of the squeezing tool 52, the cross-sectional configuration of at least the tapered portion 28 of sleeve 20, as illustrated in Figure 3, a forceps and/or through the use of folding guides positioned on the internal surface of the lumen of collet 18. Alternatively, the lens can be loaded and advanced past the tapered portion of the sleeve, in whole or in part through the use of forceps or other devices. A sleeve stabilizing device is provided in FIG. 19 to assist in loading an implant. This device is discussed *infra*.

There are other configurations for insertor devices within the scope of this invention. In another example, the device is a front loading insertor device. Referring now to Figure 10a, which illustrates in cross-section a preferred embodiment of a front-loading device for insertion of an implant in the body. The device 100 includes a hand-piece 112 and a pusher element 114. The hand-piece 112 preferably includes an elongate body and a tapered portion 120 with distal opening 121.

The pusher element 114 includes a sleeve holder 115. Sleeve holder 115 could take a variety of forms such as a post, one or more blunt barbs, one or more grooves, or the like. Pusher element 114 further includes blades 122 mounted on distal block 124 in pusher element 114. Blades 122 pass on each side of sleeve holder 115. The device further includes a sleeve 116 affixed to sleeve holder 115. Sleeve 116 extends in a reverse orientation as compared to the sleeve orientation of Figure 1. In Figure 10a, sleeve 116 is illustrated with a substantially tubular portion 117, a tapered portion 119, preferably at least one pleat 113 and a first opening 118.

In this embodiment a lens or other implant is loaded into the sleeve using the methods disclosed in association with Figure 2 except that what is the second opening in Figure 2 is now affixed to sleeve holder 115 in Figure 10a. A forceps can be initially used to position an implant in first opening 118 or to position the lens completely in the tubular portion of the sleeve. A squeezing tool 52 or a

forceps can then be used to urge the implant just past the tapered portion 119 of the sleeve or at least toward what was the second opening of the sleeve of Figure 2 and is now that portion of the sleeve affixed to sleeve holder 115 (Figure 10b).

Once the lens is loaded, that part of sleeve 116 including the first opening 118 and the tapered portion 119 are separated from the portion of the sleeve including the lens. In some embodiments, the sleeve 116 can be cut either with a sharp blade or scissors. Alternatively, a guillotine-type device can be used to sever the sleeve as a blunt-cut, a beveled cut, and the like.

Pusher element 114 is advanced toward tapered portion 120 of hand-piece 112. With this movement, blades 122 advance or mobilize the lens, again by squeezing or urging, into the tapered portion 120 of hand-piece 112, as illustrated in Figure 10b.

In yet another embodiment of this invention, the device is supplied pre-assembled with a sleeve having a lens positioned therein. Preferably the lens is supplied in a substantially unfolded state, but those of ordinary skill in the art will understand that with the development of new or different lens materials or configurations it may be possible to supply the device with a sleeve and a lens, or other implant, deformed within the narrow portion of the sleeve, ready for insertion.

In an embodiment, illustrated in Figure 11, a device 200, having a hand-piece 205 can be prepared in one piece or in two pieces. A single-piece hand-piece is illustrated in Figure 11a. Here, the device includes a hand-piece 205 and a pusher element 204. The hand-piece 205 preferably includes an elongate body with a proximal flange 203, a tapered portion 206 and a lumen 202. The hand-piece 205 includes a distal opening 208. The pusher element 204 includes a sleeve holder 210. Sleeve holder 210 can take a variety of forms, as described above. Pusher element 207 further includes blades 212 mounted on a proximal block 214 of pusher element 207. Blades 212 pass on each side of sleeve holder 210.

A removable key 214 is positioned on pusher element 204. Sleeve 216 is preferably provided with a lens 218 positioned therein. A first end of sleeve 216

is affixed to sleeve holder 210 and a second opening 222 of sleeve 216 is preferably sealed, such as with a cap 224 or seal.

In use, pusher element 204 is advanced toward tapered portion 206 of hand-piece 205. With this movement, blades 212 advance the lens into the tapered portion 206 of hand-piece 205, as illustrated in Figure 11b.

The pushing mechanism of Figure 11 is a multi-step mechanism, here a two-step pushing mechanism. A key 214 is removed from the pusher element 204 after pusher element 204 has been partially advanced. Now pusher element 204 can completely advance toward the distal portion of the device, blades 212 are free to advance the lens with pusher element 204 and the lens is moved through sleeve 216, out of device 200 and into the eye, as illustrated in Figure 11c. Multi-step pushing mechanisms are useful for increasing control over the release of the lens from insertor devices.

In another embodiment of the insertors of this invention, the hand-piece is prepared in multiple pieces, preferably in two pieces. This is particularly useful where the insertor is provided preassembled with a lens positioned in a sleeve. An example of this embodiment is provided in Figure 12. Here the device 250 includes a hand-piece 252 that further includes a distal portion 254 at the distal aspect of the hand-piece and a proximal hand-piece portion 256. The distal portion 254 includes a tapered nose 258 including a distal opening 260. A septum 262 preferably traverses the lumen of hand-piece 252 and includes a sleeve holder 264. Sleeve holder 264 is available to secure a sleeve 266 onto the device 250. A pusher element 268 includes an elongate shaft to mate with the lumen of hand-piece 252 and at least one blade, and preferably two blades 270 are preferably affixed thereto. The internal surfaces of the distal portion 254 of hand-piece 252 can include external folding guides 272. One example of these guides is provided by cross section in Figure 12b. The folding guides are termed external folding guides to differentiate these guides from the cross-sectional configuration of the sleeve that provides internal folding guides for the lens (such as the pleats and the cross-sectional configurations of Figure 3). The external folding guides 272 can take a variety of configurations and in a preferred embodiment, the cross section of distal portion 254 is substantially

rhomboid in cross-section with preferably two grooves to urge the lens into a folded conformation. Other cross-sections to distal portion 254 are possible as are other folding guides. Other folding guides are discussed in U.S, Pat. No. 5,275,604 to Rheinish et al.

Referring again to Figure 12a, a lens 274 is preferably supplied in sterile form in a capped 276 or otherwise sealed sleeve 266. Optionally the sleeve can be supplied preloaded with a buffer compatible with the eye, or with a solution compatible with another portion of the body receiving the implant. During assembly, the lens 274 is positioned in the sleeve 266 and sleeve 266 is affixed to device 250 via sleeve holder 264. Hand-piece 252 portions 254 and 256 are assembled on the devices to surround the sleeve 266 and lens 274. Hand-piece 252 portions 254 and 256 can be joined by a variety of means including, but not limited to, screw-type threads, grooves, notches, clamping mechanisms, snapping mechanisms, adhesives, and the like. Preferably, once assembled, the hand-piece 252 is not readily separable nor is the hand-piece preferably separable from the pusher element 268.

In use, cap 276 is removed from sleeve 266. Pusher element 268 is advanced toward distal portion 254 of hand-piece 252 to advance blades 270 behind lens 274 and advance lens 274 from the sleeve through opening 260 and into the eye. Preferably, after use, device 250 is disposed. It is noted that the insertor of Figure 12 can also incorporate the two-part pushing element design of Figure 11.

Sleeve 266 is preferably provided preassembled on the device with the lens in place and affixed to sleeve holder 264. Sleeve 266 preferably includes a suitable lubricant, a friction reducing material, implant stabilizer or buffer. Where a lubricant or buffer is not included with the implant, the sleeve can be filled with a suitable lubricant or buffer before use.

In another variation of this invention, the pusher element can be advanced using a threaded mechanism, such as screws, rack and pinion, or any other mechanism. These mechanisms can provide added control when the lens is being advanced by the blades.

In another preferred device 300 according to this invention (see Figure 13), a hand-piece 312 preferably includes an elongate body having a proximal end 314 and a distal end 316. The distal end 316 preferably includes a tapered portion 318 and a canal 320 communicating with a lumen 322. The canal 320 also communicates with a slot 324 that is positioned proximal to canal 320 on hand-piece 312. A hole 326 is positioned from slot 324 to an external aspect of hand-piece 312 and is adapted to receive a sleeve clamping thumbscrew 327. Sleeve 328 is a flexible, compressible sleeve with a first opening 330, a second opening 332 and a tapered portion 334 positioned therebetween. In a preferred embodiment, the second opening is preferably beveled. An implant, such as a lens, is introduced into sleeve 328 and advanced toward the distal portion of the sleeve either using the squeezing tool 52, as illustrated in Figure 2, or by gently urging the implant into the sleeve, past the tapered portion using a forceps, or the like.

Once sleeve 328 is loaded with an implant, the sleeve is positioned in hand-piece 312. The second opening 332 of sleeve 328 is passed through lumen 322 and the first opening 330 of the sleeve 328 is positioned into slot 324. Sleeve clamping thumbscrew 327 is tightened to immobilize sleeve 328. In one aspect of this embodiment, a squeezing blade assembly 336 including at least one blade, and preferably two blades 338 are connected to a thumb-engaging portion 340. The squeezing blade assembly 336 is positioned on either side of sleeve 328 and before thumb-engaging portion 340 is mobilized, blades 338 are positioned just proximal to lens 342. Movement of the thumb-engaging portion 340 along the axis of hand-piece 312 toward the distal end 316 of device 300 results in the egress of lens 342 from sleeve 328. In an alternative embodiment of the device of Figure 13, the thumb screw 327 is replaced with a ring clamp to immobilize the sleeve 328. Thumb knobs can be added to the squeezing blade assembly as desired.

In yet another embodiment, the sleeve can be used separately as an insertor without using the hand-piece portion of this invention. For example, a sleeve, such as illustrated in Figure 2 is loaded with an implant, such as a lens, as provided above. The sleeve itself can be used to directly deliver the lens by

clamping a portion of first opening 24 of the sleeve with a forceps or suitable hemostat-type device. In this embodiment a pushrod, such as a small cylindrical bar, can be introduced into the sleeve after the implant has been inserted and positioned in the sleeve by squeezing or urging the implant towards the distal end. The implant is mobilized using direct force applied to the implant by the pushrod to introduce the implant into the body. Alternatively, a squeezing tool, such as that illustrated in Figure 2, or a modification of the squeezing tool (for example, with an added handle, or the like) can be used to position the lens in the sleeve or a squeezing tool can be use to advance the implant into the tapered portion of the sleeve, toward the second opening of the sleeve and past the second opening and into the body. In a further embodiment, the implant is advanced through the sleeve using fingers to gently urge the lens by nutating and/or gently pinching the sleeve behind the implant. In yet a further embodiment, the sleeve can be rolled from the first opening 24 to the second opening to advance the lens or another implant through a sleeve. In some of these embodiments, a squeezing motion is used to advance the lens, at least in part, through the sleeve. The ability of the sleeve to be squeezed through a squeezing device, manipulated by fingers to advance an implant or to roll up a portion of the sleeve to advance the implant also speaks to the nature of the sleeve material. The flexible, compressible, malleable sleeve is prepared from a material that permits ready manipulation of the sleeve as described herein.

As noted above, the devices of this invention can position implants in the eye or elsewhere in the body. For example, in a preferred embodiment, illustrated in Figure 14a, the implant is a lens 450. The lens is advanced using blades 416 on sleeve 420 to squeeze a lens 450 into the eye, generally illustrated as 452. Figure 14b is a cross section of the eye with a cornea 422, a natural lens 424 and the distal portion 410 of a device according to this invention including blades 416 and a sleeve 420 to advance a lens into the eye. The lens is not necessarily an intraocular lens, but the lens can take the form of an implantable contact lens (ICL) shown in Figure 14b positioned just anterior to the natural lens 424. Alternatively, the devices of this invention can be used to implant a flexible contact lens onto the surface of the cornea, the device can be used to

introduce devices to treat glaucoma or to implant a variety of flexible, solid implants elsewhere in the body.

In several embodiments of this invention, the invention provides a means for compressing a sleeve to advance an implant from the sleeve into a portion of a body. Figure 15 is an enlarged partial cross-sectional view of the interface between one means for compressing a sleeve in accordance with the present invention. The sleeve 520 includes two side walls 520a and 520b. At least a portion of the side walls 520a and 520b is compressed in the preferred embodiment by blades 516a and 516b as depicted in Figure 15. Those of skill in the art will, however, understand that many other means for compressing sleeve 520 could be substituted for the disclosed blades.

The compressed portion of the sleeve 520 is then advanced in the direction of arrow 510 towards the implant 550 located between side walls 520a and 520b in sleeve 520. As a result, the blades 516 also function as one preferred embodiment of the means for advancing the compressed portion of sleeve 520 towards the distal end of sleeve 520. Those of skill in the art will, however, understand that many other means for advancing the compressed portion of sleeve 520 could be substituted for the disclosed blades. It is the gentle, squeezing action of sleeve 520 on implant 550 that provides the ability of the present intention to gently deliver an implant in contrast to the known methods.

Those of ordinary skill in the art will recognize that this device has been described by way of using a lens. For other implants, the sleeve configuration can be varied somewhat. For example, while the sleeve would preferably still include a first opening and a second opening, the sleeve may not need a tapered portion, particularly where deformation of the implant prior to insertion is not necessary. Moreover, also depending on a particular insertion application, the dimensions of the device and the dimensions of an incision size can change for a particular application. The cross-section of the sleeve can be narrower or wider, the blade length, sleeve length, hand-piece length can be adjust by ordinary skill in the art to accommodate a variety of implants.

Those of skill in the art will realize that although the devices described in this invention are operated using manual force, similar devices can be prepared using pneumatic, servo-mechanisms including electrical and hydraulic forces, extended flexible cable devices, such as via a foot pedal, or the like without detracting from the scope of this invention.

In one embodiment of this invention, the device is supplied in kit form with an insertor, such as insertor 10 (Figure 1), a sleeve, in one or two pieces, either empty or already containing the implant and optionally a squeezing tool such as squeezing tool 52. The implant can be supplied with the device or purchased separately. Preferably the device is used to implant a foldable lens and preferably the foldable lens is an intraocular lens.

In another aspect of this invention, the invention includes a sleeve supporting device such as a sleeve holder 650 as illustrated in FIG. 19. The sleeve holder 650 is preferably prepared from a substantially rigid material such as a plastic, including thermoplastic polymers, as well as acrylics, hard silicones, nylon, rubber, and the like. In a preferred embodiment the sleeve holder 650 is prepared from a sufficiently clear material to permit visualization of the implant in the sleeve when the sleeve is in position in the holder. The sleeve holder includes a hollowed portion that is slightly larger but generally and preferably conforms in shape to the shape of sleeve 652 or another sleeve, according to this invention. The sleeve of FIG. 19 includes a first opening 654 and a second opening 656. The first opening 654 is preferably larger than second opening 656 and preferably the diameter of first opening 654 is from about 4.5 mm to about 10 mm and the diameter of the second opening 656 is from about 1.5 mm to about 4 mm. A preferred length of the holder is from about 2 cm to about 4 cm. The sleeve holder adds support to the flexible deformable sleeve during insertion of an implant, such as an intraocular lens 658 into the sleeve. The sleeve holder can take any of a variety of shapes and preferably the shape and size of the holder permit it to be held in one hand while inserting an implant into a sleeve in the holder with the other hand. In FIG. 19, the holder is rectangular in shape, but those of ordinary skill in the art will recognize that a variety of holder shapes and sizes can be prepared to accommodate sleeves in view of this disclosure.

Importantly, the pleats 38 in sleeve 20 of FIG. 2 are optional when a sleeve holder such as sleeve holder 650 is used. The combination of a sleeve of this invention with a sleeve holder forms an implant loading system of this invention.

In use, the sleeve is positioned in the block before or after lubricating the sleeve with a suitable friction-reducing agent or buffer. The intraocular lens 658 is inserted into first opening 654 using a forceps 660, fingers, or the like. The lens is urged into the first opening and is positioned preferably past the tapered portion 662 of sleeve 652 and at least partially into the tubular portion 655 of the sleeve. The sleeve is preferably able to distend or stretch to accommodate the additional bulk of the forceps when the forceps is introduced into the sleeve with the implant. Optionally, the implant can be deformed slightly to encourage folding in a desired direction when the implant is introduced into the sleeve, using for example, lateral pressure while introducing the lens into the tapered portion and into 662 at least a part of the tubular portion. The forceps 660 is removed from the first opening 654 and the sleeve 652 is removed from holder 650. The sleeve holder is preferably reusable and can optionally be disposable or sterilizable such as by autoclaving, ethylene oxide, or ultraviolet light.

Not only is the holder capable of being sterilized, but other components of this invention including the hand-pieces, ring clamps, collets, pusher-elements, and the like can be sterilized for reuse.

The invention also relates to a kit comprising a sleeve of this invention, an implant, such as an intraocular lens, a corneal implant or another implant according to this invention. Optionally, the kit includes a holder for the sleeve, such as provided in FIG. 19 and optionally the kit includes an insertor device according to this invention. Further the elements of the kit are packing in a tray or package suitable for shipping.

FIG. 18 illustrates an additional insertor embodiment that employs a flexible, deformable sleeve of this invention together with a pushrod to mobilize an implant from an insertor into a portion of the body. In FIG. 18a, an insertor 700 includes a flexible sleeve 702, a collet 704, and a ring clamp 706. A hand-piece 708 includes a pusher-element 710 or other means for mobilizing a pushrod 712. The pushrod 712 is preferably rounded at the tip 714 to minimize

trauma to the implant when the implant is mobilized in the sleeve 702 but the pushrod could also be flattened or grooved. The pushrod 712 is preferably prepared from either the same or similar material as the hand piece or alternatively prepared from stainless steel, TEFLON, acrylic, vinyl, polysulfone, or the like.

To assemble, the sleeve 702, collet 704 and ring clamp 706 can be assembled as described in regard to FIG. 16. The pushrod 712 preferably extends from the hand-piece sufficiently that it can be positioned within the first opening of the sleeve 702 as the ring clamp 706 is position and affixed to the hand-piece 708. At least one indexing extension 713 preferably extends from the distal portion of the hand-piece to key or mate with the proximal portion of the collet (as illustrated in the proximal portion of the collet of FIG. 16). The extensions prevent rotation of the collet relative to the hand-piece as the ring clamp is secured to the hand-piece. The ring clamp 706 secures the collet to the device and provides a clamping force to immobilize sleeve 702 between slits 716 of collet 704.

In another variation, the sleeve with an implant is positioned over the pushrod 712. Where an intraocular lens is used, care is taken to align the pushrod with the body of the lens so that the haptics are free to move within the sleeve. Next, collet 704 is placed over the sleeve and positioned onto hand-piece 708 using extensions 713. The ring clamp 706 is next positioned onto the device.

The assembled device is provided in FIG. 18b and the distal end of collet 704 for the pushrod device is preferably illustrated in FIG. 4a. A cross-section of the device through E-E of FIG. 18b is illustrated in FIG. 18c. Here ring clamp 706 surrounds the proximal portion of collet 704. Sleeve 702 is positioned within the lumen 718 of collet 704 with pushrod 712 positioned within sleeve 702. Ring clamp 706 provides a clamping force to immobilize sleeve 702 within the device 700. The ring clamp 706, the screw 327 of FIG. 17 and other pressure fit elements are contemplated to immobilize the sleeve of this invention in the insertor.

Once assembled, an incision into the body is prepared and the sleeve 702 is positioned in or adjacent to the incision. The pushrod 710 is gently activated to advance the pushrod toward the distal portion of the device, thereby mobilizng the implant in the sleeve 702 and from the sleeve into the body. While either the blade embodiment or the pushrod embodiment will function with the flexible, deformable sleeves of this invention, the blades may be better suited for more fragile implants. Advantageously, the pushrod device in combination with the sleeve of this invention requires little force to mobilize an implant so that the likelihood of damaging the implant with the pushrod is low.

In another aspect of this invention, the invention relates to a method for making a sleeve of this invention. A variety of methods are available in the art for making the sleeves of this invention from a variety of flexible, distendable, compressible materials. These methods include, but are not limited to, injection molding and pressing or compressive forces to form the sleeve from existing materials.

In a preferred embodiment, a compressive force is used to compress and distend a flexible and distendable material to form a sleeve. In a preferred method, ETFE or PTFE tubing is subjected to a squeezing and compressive force such as a hydraulic or screw-jack press to form, squeeze and flatten the tubing into the widened first opening of the sleeve so that the width is wider than the initial tubing diameter and to form the tapered portion of the sleeve. Heat can be added to the compressive force to ease compression, for example, for higher tensile strength plastics. Preferred temperatures should be below the melting temperature of the tubing and preferably for PTFE tubing less than about 232 °C. However, in a preferred embodiment the press does not include a heat source and the press uses cold flow squeezing to flatten and expand the PTFE or ETFE tubing to form a wider implant loading zone (i.e., the first opening of the sleeve) relative to the tubing diameter.

Referring now to FIG. 20, and following the direction of arrow 801, FIG. 20 illustrates a preferred method for producing the sleeves of this invention using preformed tubing 800, where the tubing 800 is malleable and substantially

transparent to permit visualization of an implant when positioned therein and where the tubing is suitable to distension and compression.

The tubing 800 is positioned between a press, preferably comprising two compressive surfaces 802 and 804. Tubing 800 is preferably extruded tubing and preferably PTFE or ETFE. Preferred PTFE tubing is about 2.5 mm in diameter with a preferred wall thickness of about .15 mm but those of ordinary skill in the art will recognize that a variety of sizes of tubing and a variety of compressive forces can be used to prepare sleeves of this invention in a variety of sizes and wall thicknesses without undue experimentation. The tubing is subjected to a compressive force sufficient to permanently flatten or distend and compress the tubing. A preferred distended tubing shape is provided in FIG. 20 as distended tubing portion 806. Preferred distension and compressive forces will depend on the tubing material but are preferably between about 1,000 psi to about 25,000 psi and more preferably from about 5,000 psi to about 10,000 psi. Preferably the force is applied perpendicular to the tubing. Referring again to compressive surfaces 802 and 804, preferably at least one of the compressive surfaces includes a sloping portion 808 that slopes away from at least one of the compressive surfaces. The angle of the sloping portion relative to the compressive surface can vary but is preferably at least 0.5° and in a preferred embodiment is about 1°. Preferred post-compression wall thicknesses for 2.5 mm PTFE tubing are about 0.01mm to about 0.10 mm with a preferred post-compression wall thickness of about .08 mm. Preferably the post-compression wall thickness of the sleeve is less than two-thirds and preferably about one-half of the original wall thickness of the non-compressed tubing and is preferably further distended at least 1.6 of the original diameter of the tubing and more preferably about 3 times the diameter and preferably from about 2 to about 4 times the original diameter of the tubing

Following application of a compressive force, the distended tubing portion 806 is cut, such as with a cutting blade 810 or another device. In addition, the tubing is further cut in a non-distended region, if needed, as illustrated using cutting blade 812. Cutting blade 812 can be angled, if desired, to produce a beveled effect. Advantageously, using this method, each region of

distended tubing can be used to prepare two sleeves 814 and 816 as illustrated in FIG. 20. The mechanics behind the compressive surfaces can vary such that a mechanized press, a hydraulic press, a hand cranked press or the like can be used, as suited to a particular application. Further, the sleeves can be prepared individually, or, as illustrated in FIG. 20 in a production line. As discussed above, the final length of the sleeve, the shape of the distended portion and the length of the non-distended portion as well as the grade of the taper of the sleeve can vary depending on the dimensions of the insertor.

It will be appreciated by those skilled in the art that while the invention has been described above in connection with particular embodiments and examples, the invention is not necessarily so limited and that numerous other embodiments, examples, uses, modifications and departures from the embodiments, examples and uses may be made without departing from the inventive scope of this application.

What is Claimed is:

1. A device for positioning a flexible implant in a portion of the body comprising;

a compressible sleeve to contain an implant; and means for squeezing the compressible sleeve to advance the implant from the sleeve.

2. The device of Claim 1 wherein the flexible implant is a lens.
3. The device of Claim 2 wherein the flexible implant is an intraocular lens.
4. The device of Claim 2 wherein the intraocular lens is a single-piece lens.
5. The device of Claim 2 wherein the intraocular lens is a multi-piece lens.
6. The device of Claim 1 wherein the implant is a subcutaneous implant.
7. The device of Claim 1 wherein the means for squeezing the compressible sleeve comprises at least one blade.
8. The device of Claim 7 wherein the at least one blade comprises two blades.
9. The device of Claim 1 wherein the means for squeezing the compressible sleeve is a ring.
10. The device of Claim 1 wherein the means for squeezing the compressible sleeve is a squeezing tool.
11. The device of Claim 1 further comprising a housing for the sleeve.
12. The device of Claim 11 wherein the housing comprises a hand-piece.
13. The device of Claim 11 wherein the housing comprises a pusher element.
14. The device of Claim 13 wherein the means for squeezing the compressible sleeve is affixed to the pusher element.
15. The device of Claim 1 wherein the sleeve is a flexible polymeric material.
16. The device of Claim 1 wherein the sleeve comprises a first opening, a second opening and a tapered portion, wherein the first opening is larger than the second opening.
17. The device of Claim 16 wherein the sleeve further comprises at least one pleat.
18. The device of Claim 17 wherein the sleeve comprises a plurality of pleats.
19. A device for introducing an implant into a portion of the body comprising:

a housing comprising a hand-piece having a lumen, means for stabilizing a compressible sleeve in the lumen and a pusher element wherein the pusher element comprises at least one blade.

20. The device of Claim 19 wherein the means for stabilizing a compressible sleeve is a collet.

21. The device of Claim 19 wherein the means for stabilizing a compressible sleeve is a sleeve holder.

22. The device of Claim 21 wherein the sleeve holder is a groove.

23. The device of Claim 21 wherein the sleeve holder is at least one post.

24. The device of Claim 19 wherein the blade contacts the sleeve when the sleeve is positioned in the lumen.

25. The device of Claim 19 further comprising a compressible sleeve.

26. The device of Claim 25 further comprising an implant.

27. The device of Claim 26 wherein the implant is a lens.

28. The device of Claim 27 wherein the lens is an intraocular lens.

29. The device of Claim 26 wherein the implant is an implant to treat glaucoma.

30. The device of Claim 27 wherein the lens is a contact lens.

31. The device of Claim 27 wherein the lens is an implantable contact lens.

32. The device of Claim 25 wherein the compressible sleeve comprises a first end and a second end and wherein the first end is affixed to the housing.

33. The device of Claim 26 wherein the implant is supplied in the compressible sleeve.

34. The device of Claim 32 wherein the second end of the sleeve comprises an opening extending from the lumen of the housing.

35. The device of Claim 34 wherein the second end of the sleeve comprises a cap.

36. The device of Claim 34 wherein the second end of the sleeve is flared.

37. The device of Claim 34 wherein the second end of the sleeve is tapered.

38. The device of Claim 36 wherein the second end is tapered from a first cross-section to an opening having a second cross-section, wherein the opening is sized to receive an implant.

39. The device of Claim 20 wherein the collet comprises a proximal end, a distal end and a lumen extending between the proximal end and the distal end.

40. The device of Claim 39 wherein the collet further comprises at least one slit extending from the proximal end of the collet.

41. The device of Claim 39 wherein the distal end of the collet has a cross-sectional configuration selected from the group consisting of a scrolled pattern, a circle, a rhombus and a winged circle.

42. The device of Claim 39 wherein the lumen of the collet is tapered in cross-sectional dimension from the proximal end of the collet to the distal end of the collet.

43. The device of Claim 39 wherein the surface of the lumen of the collet comprises external folding guides.

44. A compressible sleeve comprising a flexible polymeric material, the sleeve further comprising a first opening and a second opening, and an implant wherein the size of the first opening is greater than the size of the second opening.

45. The sleeve of Claim 44 wherein the implant is a lens.

46. The sleeve of Claim 44 wherein the implant is a glaucoma implant.

47. The sleeve of Claim 45 wherein the implant is an intraocular lens.

48. The sleeve of Claim 44 wherein the implant is prepared from a soft polymeric or gelatinous material.

49. The sleeve of Claim 44 further comprising at least one cap or seal.

50. The sleeve of Claim 49 further comprising a viscoelastic solution or a buffered solution.

51. The sleeve of Claim 44 wherein the sleeve is prepared in two pieces.

52. A compressible sleeve comprising a flexible polymeric material, the sleeve further comprising a first opening, a second opening, and a tapered portion, wherein the size of the first opening is greater than the size of the second opening and wherein at least the tapered portion has a cross-sectional configuration selected from the group consisting of one pleat, a plurality of pleats, a V-shape, an oval, a circle, and an envelope.

53. The sleeve of Claim 52 further comprising an implant.

54. The sleeve of Claim 52 wherein the sleeve is a multi-piece sleeve.

55. A flexible, elongated, compressible sleeve housing a foldable lens.

56. A device comprising a pushing mechanism, a squeezing means to advance an implant in the device, a flexible, compressible sleeve and means for immobilizing the sleeve in the device.

57. A kit comprising:

a device comprising a pushing mechanism, a squeezing means to advance an implant in the device and means for immobilizing the sleeve in the device; and

a flexible, compressible sleeve.

58. The kit of Claim 57 further comprising a squeezing tool.

59. The kit of Claim 57 further comprising an implant.

60. The kit of Claim 57 wherein the implant is a lens.

61. A device for introducing an implant in the body comprising:

a housing comprising a first end and a second end, with an opening positioned at the second end;

a compressible sleeve; and

a pushing mechanism affixed to at least one squeezing blade positioned within the housing wherein the squeezing blade contacts the compressible sleeve.

62. The device of Claim 61 wherein the pushing mechanism is a multi-step pushing mechanism.

63. The device of Claim 61 wherein the sleeve is affixed to a sleeve holder positioned in the housing.

64. The device of Claim 61 further comprising an implant positioned within the sleeve.

65. The device of Claim 61 wherein the housing further comprises a tapered portion at the second end.

66. The device of Claim 61 wherein the housing further comprises external folding guides within the housing.

67. The device of Claim 61 wherein the sleeve comprises a cross-sectional configuration selected from the group consisting of one pleat, a plurality of pleats, a V-shape, an oval, a circle, and an envelope.

68. The device of Claim 61 wherein the sleeve comprises a first end affixed to the sleeve holder and a second end, wherein the second end is tapered from a first cross-section to an opening having a second cross-section, wherein the opening is sized to receive an implant.

69. The device of Claim 64 wherein the sleeve extends from the opening in the housing.

70. The device of Claim 64 wherein the sleeve further comprises a cap or a seal.

71. The device of Claim 61 wherein the sleeve is positioned in the housing using a clamp.

72. The device of Claim 71 wherein the device further comprises a collet.

73. The device of Claim 72 wherein the collet comprises a proximal end, a distal end and a lumen extending between the proximal end and the distal end.

74. The device of Claim 73 wherein the collet further comprises at least one slit extending from the proximal end of the collet.

75. The device of Claim 73 wherein the distal end of the collet has a cross-sectional configuration selected from the group consisting of a scrolled pattern, a circle, a rhombus and a winged circle.

76. The device of Claim 73 wherein the lumen of the collet is tapered in cross-sectional dimension from the proximal end of the collet to the distal end of the collet.

77. The device of Claim 73 wherein the surface of the lumen of the collet comprises external folding guides.

78. The device of Claim 73 wherein at least a portion of the surface of the lumen of the collet comprises a rectangular cross section.

79. The device of Claim 61 wherein the housing further comprises a slot to receive the sleeve.

80. The device of Claim 79 wherein the sleeve is immobilized in the housing using a

screw.

81. A method for implanting an implant in a portion of the body comprising the steps of:

providing a housing comprising a first end and a second end, with an opening positioned at the second end and a pushing element affixed to at least one squeezing blade positioned within the housing;

loading an implant into a compressible sleeve and introducing the sleeve into the housing wherein the blade contacts the sleeve; and

moving the pushing element to advance the implant in the sleeve toward the opening.

82. A method for introducing an implant into a compressible sleeve comprising the steps of:

providing a sleeve comprising a first opening, a second opening, and a tapered portion positioned between the first opening and the second opening;

introducing an implant into the first opening of the sleeve; and

squeezing the implant past the tapered portion of the sleeve.

83. A method for inserting an implant comprising the steps of:

positioning an implant into a compressible, flexible sleeve; and

squeezing at least a portion of the sleeve to advance the implant through at least a portion of the sleeve.

84. The method of Claim 83 wherein the squeezing step uses a squeezing tool.

85. The method of Claim 83 wherein the squeezing step uses at least one squeezing blade.

86. The method of Claim 83 wherein the squeezing step uses a squeezing ring.

87.A device for positioning an implant within a body comprising:

a sleeve having a proximal and a distal end;

an implant located within the sleeve;

means for compressing a portion of the sleeve between the proximal end of the sleeve and the location of the implant within the sleeve;

means for advancing the compressed portion of the sleeve towards the distal end of the sleeve, whereby the implant is urged towards the distal end of the sleeve.

88. A method for positioning an implant within a body comprising:

providing an implant located within a sleeve, the sleeve having a proximal end and a distal end;

compressing a portion of the sleeve between the proximal end and the implant located within the sleeve; and

advancing the compressed portion of the sleeve towards the distal end of the sleeve, whereby the implant is urged towards the distal end of the sleeve.

89. A method according to claim 88, further comprising positioning the distal end of the sleeve within a body.

90. A method for delivering an implant within a body comprising:

providing a sleeve having a proximal end and a distal end;

introducing an implant into the proximal end of the sleeve;

compressing a portion of the sleeve between the proximal end and the implant located within the sleeve; and

advancing the compressed portion of the sleeve towards the distal end of the sleeve, whereby the implant is urged towards the distal end of the sleeve.

91. A flexible compressible sleeve comprising a first opening and a second opening with a lumen extending through the sleeve, wherein the size of the first opening is greater than the size of the second opening and wherein the thickness of a wall of the first opening is thinner than the thickness of a wall of the second opening.

92. The sleeve of Claim 91 wherein the sleeve has a length of about 10 mm to about 50 mm.

93. The sleeve of Claim 91 wherein the width of the sleeve is about 1.5 mm to about 4 mm at the second opening.

94. The sleeve of Claim 91 wherein the thickness of a wall of the first opening is about 0.01 mm to about 0.1 mm.

95. The sleeve of Claim 91 wherein the thickness of a wall of the second opening is about 1.5 mm to about 3.5 mm.

96. The sleeve of Claim 91 wherein the sleeve is distendable.

97. A flexible, compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve,

wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening.

98. A system for loading an implant comprising:

a flexible, compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve, wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening; and

a sleeve holder prepared from a substantially rigid material and comprising a lumen extending therethrough, wherein the lumen comprises a first opening and a second opening and wherein the first opening is larger than the second opening and wherein the lumen is adapted to substantially conform to the shape of the sleeve.

99. A sleeve supporting device comprising a substantially rigid body comprising a lumen extending therethrough, wherein the lumen comprises a first opening and a second opening and wherein the first opening is larger than the second opening and wherein the lumen is adapted to substantially conform to the shape of a sleeve.

100. The supporting device of Claim 99 wherein the width of the first opening is from about 4.5 mm to about 10 mm and wherein the width of the second opening is from about 1.5 mm to about 4 mm.

101. A kit comprising:

a flexible, compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve, wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening; and

an implant.

102. The kit of Claim 101 further comprising a sleeve holder prepared from a substantially rigid material and comprising a lumen extending therethrough, wherein the lumen comprises a first opening and a second opening and wherein the first opening is larger than the second opening and wherein the lumen is adapted to substantially conform to the shape of the sleeve.

103. The kit of Claim 101 wherein the implant is a flexible lens.

104. A device for introducing an implant into the body comprising:

a flexible compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve, wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening; and

a hand-piece capable of mobilizing the implant and immobilizing the sleeve.

105. The device of Claim 104 wherein the implant is a lens.

106. The device of Claim 105 wherein the implant is an intraocular lens.

107. The device of Claim 104 wherein the hand-piece comprises at least one blade to mobilize the implant by squeezing the sleeve.

108. The device of Claim 104 wherein the hand-piece comprises a pushrod positioned within the sleeve to mobilize the implant.

109. The device of Claim 104 wherein the hand-piece further comprises a pressure fit element to immobilize the sleeve in the hand-piece.

110. The device of Claim 109 wherein the pressure fit element is a collet or a screw

111. A device for introducing a flexible implant into a portion of the body comprising:

a compressible, flexible sleeve comprising a flexible polymeric material and a lumen extending through the sleeve;

an implant positioned in the sleeve; and

a hand-piece wherein the hand-piece further comprises a push-rod that extends into the sleeve.

112. The device of Claim 111 wherein the sleeve has a first opening and a second opening and wherein the width of the first opening is larger than the width of the second opening.

113. The device of Claim 111 wherein the push rod has a rounded tip.

114. A method for preparing a flexible, non-opaque sleeve comprising the steps of:

positioning a flexible, compressible, deformable tubing in a press wherein the press comprises at least two compressive surfaces;

applying a compressive force to the tubing to permanently distend at least a portion of the tubing and to form a distended portion of the tubing and a non-distended portion of the tubing;

cutting the tubing in the distended portion and cutting the tubing in the non-distended portion to form a sleeve.

115. The method of Claim 114 wherein tubing is a polymeric tubing.

116. The method of Claim 115 wherein the tubing is PTFE or ETFE.

117. The method of Claim 114 wherein the press further comprises heat.

118. The method of Claim 114 wherein the thickness of the wall of the distended tubing is at less than two-thirds of the thickness of the tubing before applying the compressive force.

119. An intraocular lens insertor, the improvement comprising the use of a flexible, compressible immobilized sleeve housing an intraocular lens wherein the lens is positioned in the sleeve before the sleeve is immobilized in the insertor.

120. A device for introducing an implant into the body comprising;

a flexible compressible sleeve wherein the sleeve comprises a first opening and a second opening and a lumen extending through the sleeve, wherein the sleeve is prepared from a non-opaque material and wherein the width of the first opening is larger than the width of the second opening;

an implant; and

a hand-piece comprising a pushrod to fit within the flexible sleeve and means for advancing the pushrod to mobilize the implant in the device.

121. The device of Claim 120 wherein the sleeve is tapered from the first opening to the second opening.

122. The device of Claim 120 wherein the thickness of a wall of the first opening of the sleeve is less than two-thirds of the thickness of a wall of the second opening of the sleeve.

123. The device of Claim 120 wherein the implant is a lens.

124. The device of Claim 123 wherein the implant is an intraocular lens.

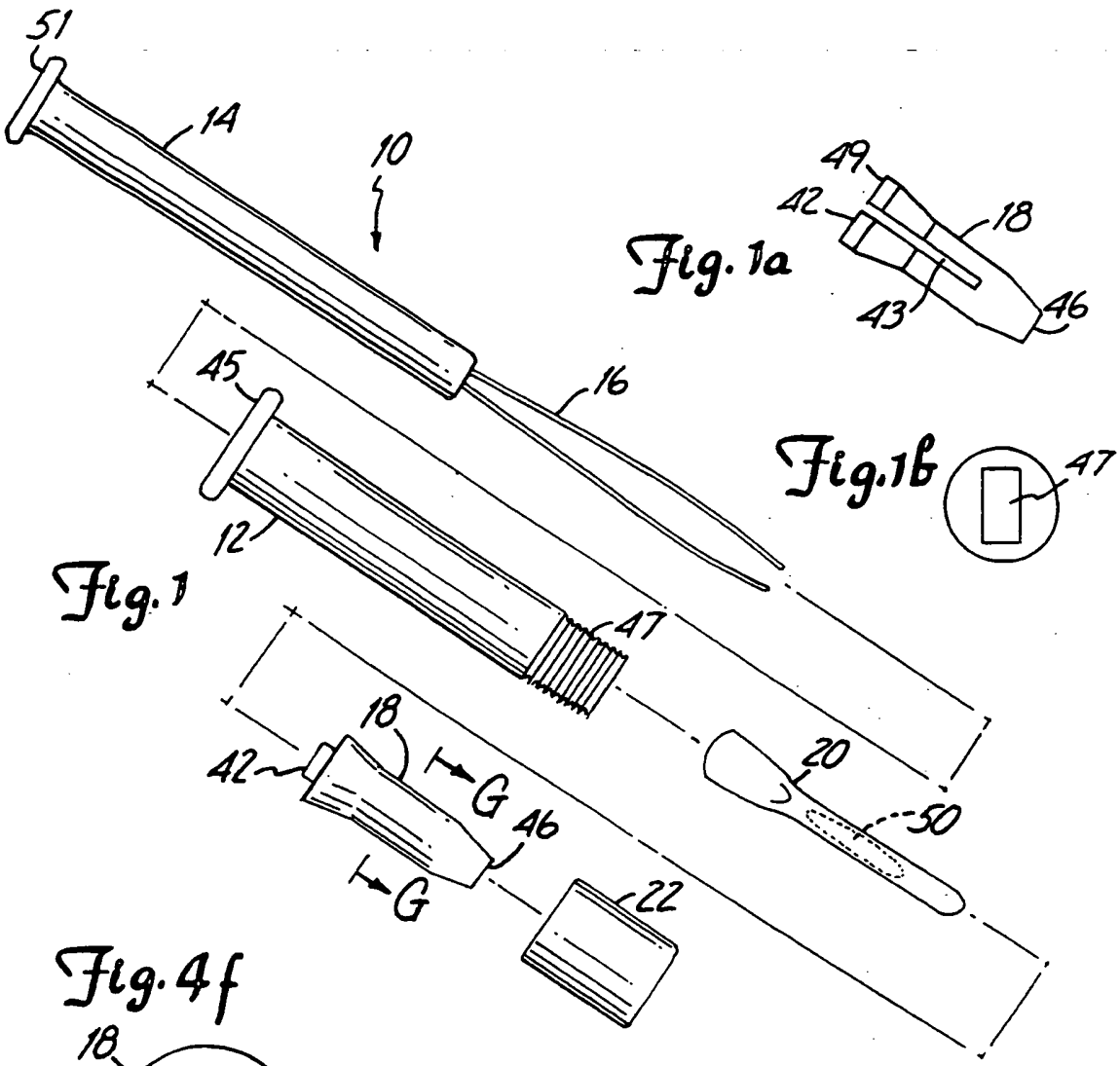


Fig. 1

Fig. 1a

Fig. 1b

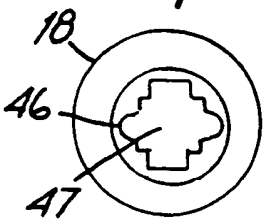


Fig. 4f

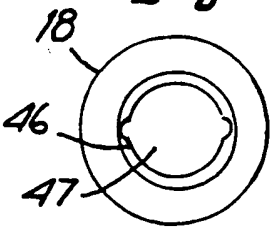


Fig. 4e

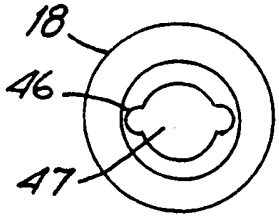


Fig. 4d

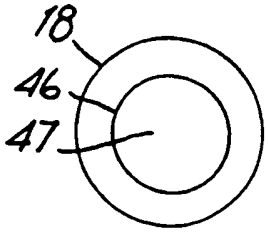


Fig. 4a

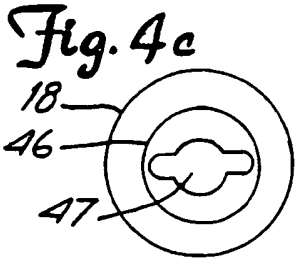


Fig. 4c

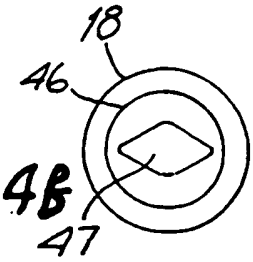


Fig. 4b

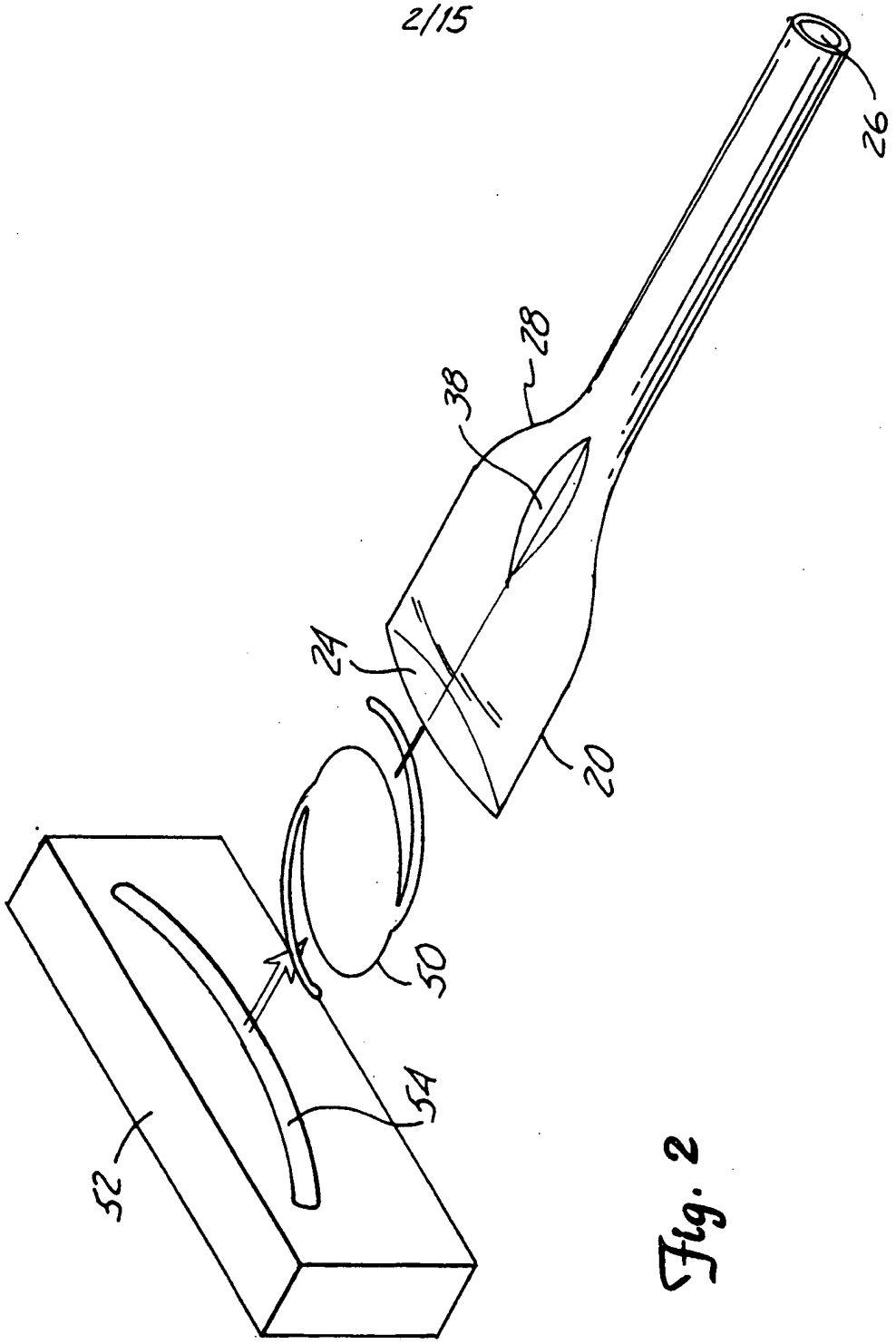


Fig. 2

Fig. 3a

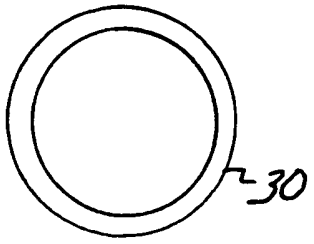


Fig. 3b

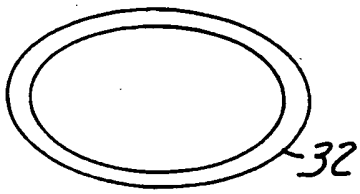


Fig. 3c

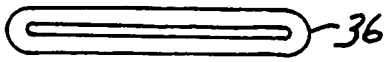


Fig. 3d

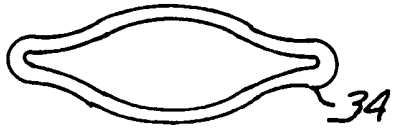


Fig. 3e

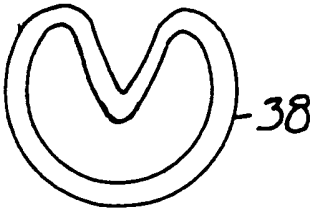


Fig. 3f

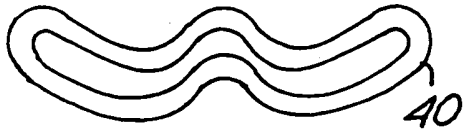


Fig. 3g

Fig. 5a

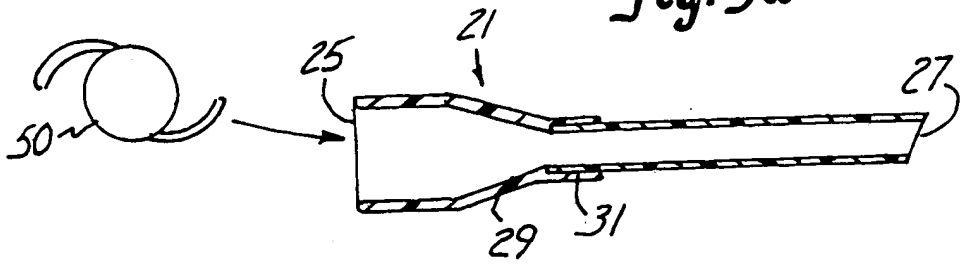
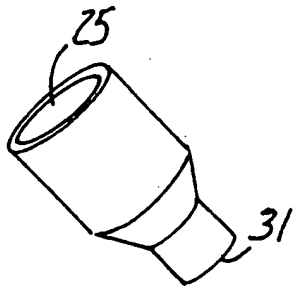
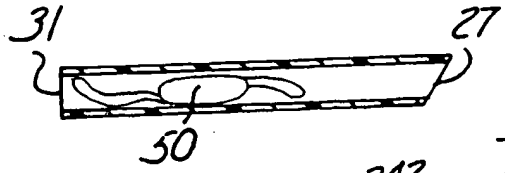


Fig. 5b





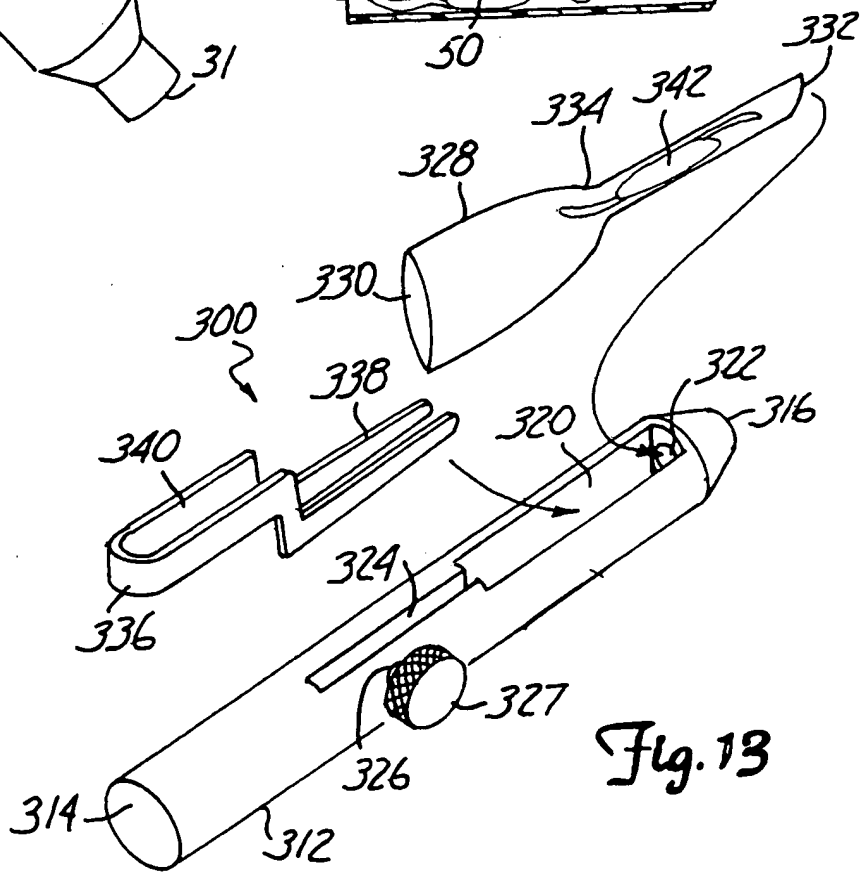


Fig. 13

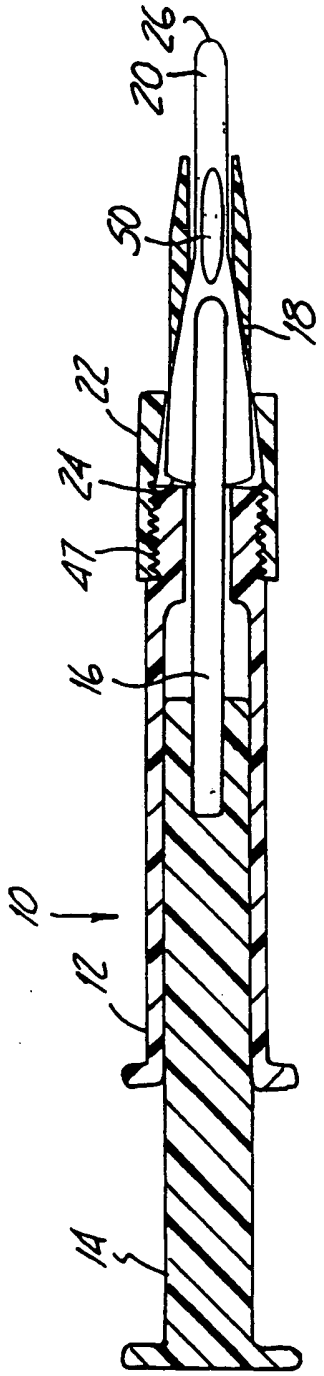


Fig. 6

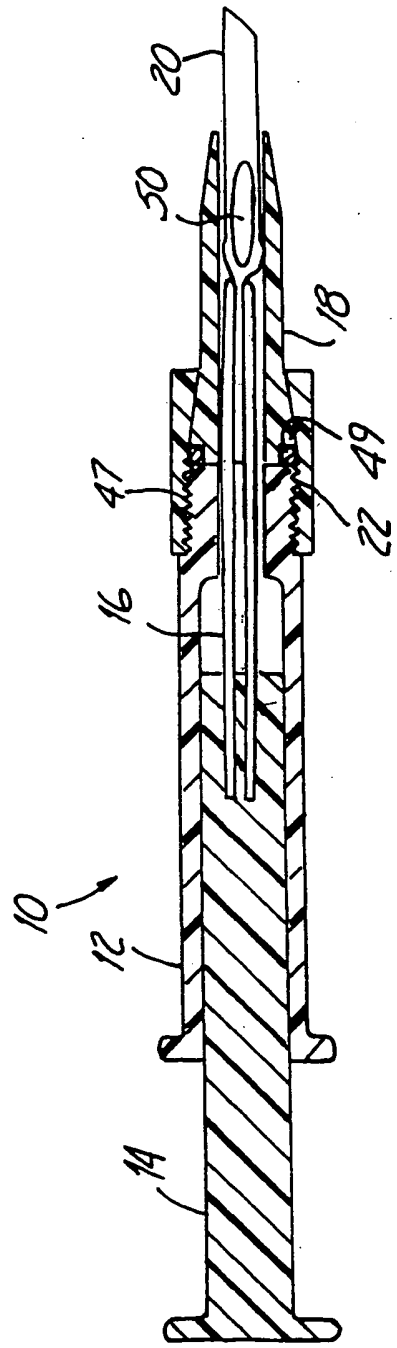


Fig. 7

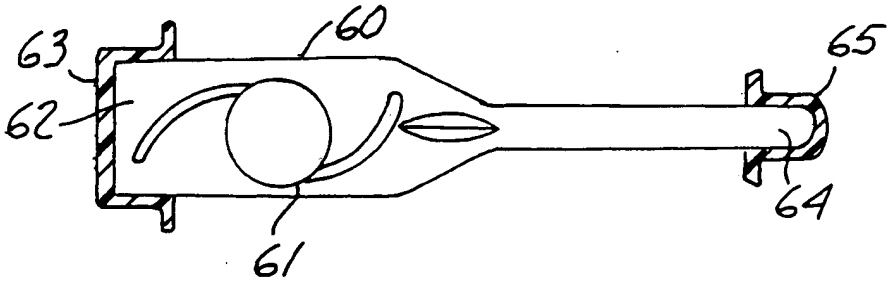


Fig. 9

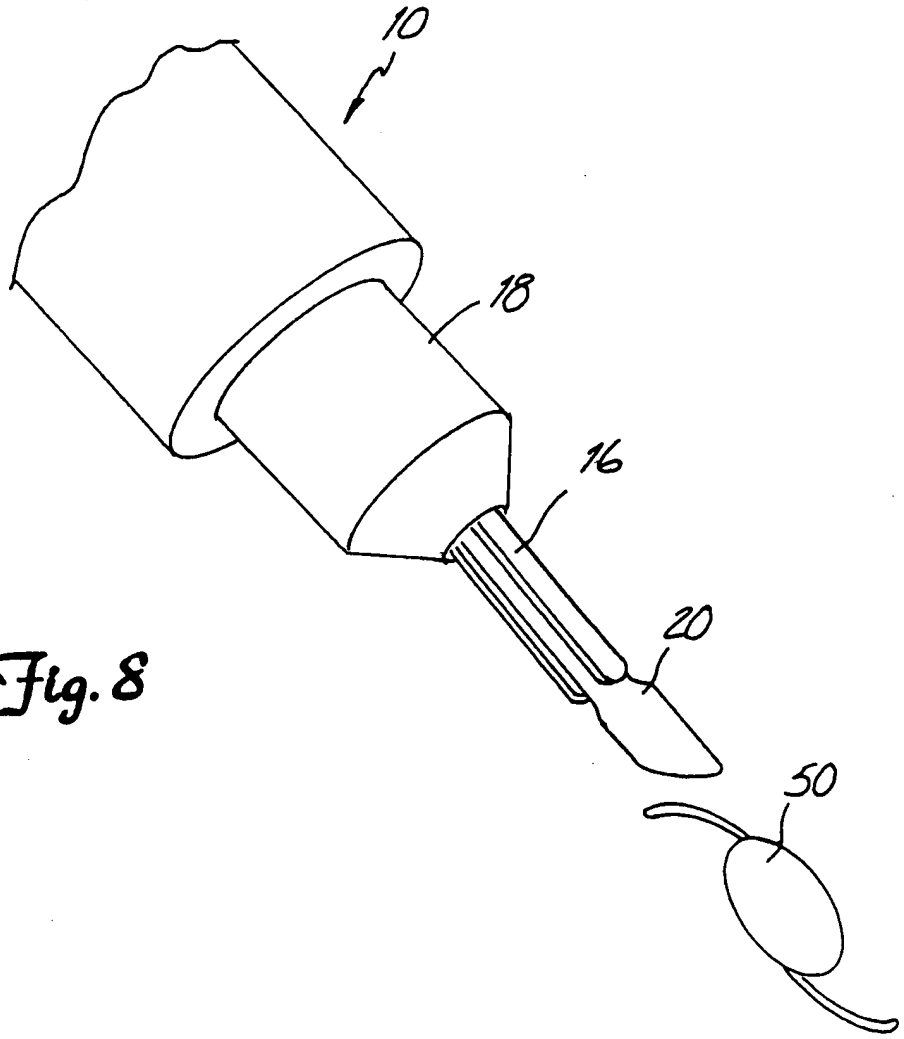


Fig. 8

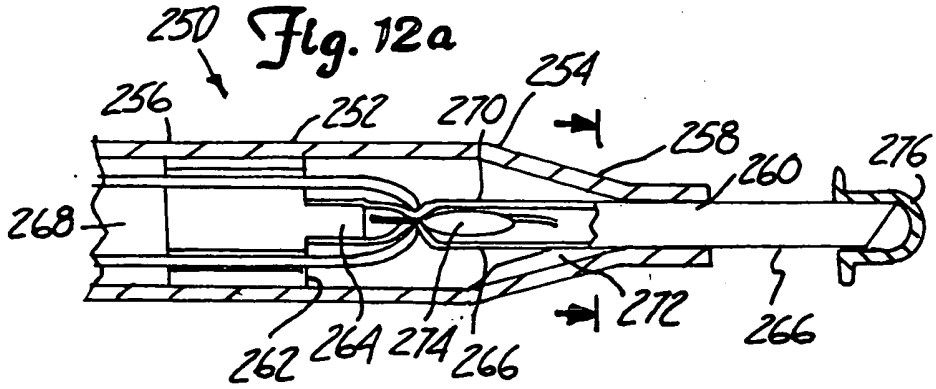


Fig. 12a

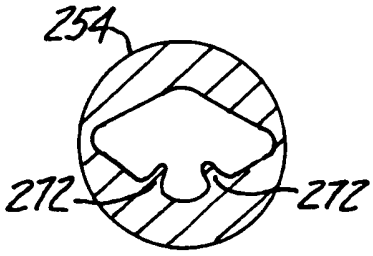


Fig. 12b

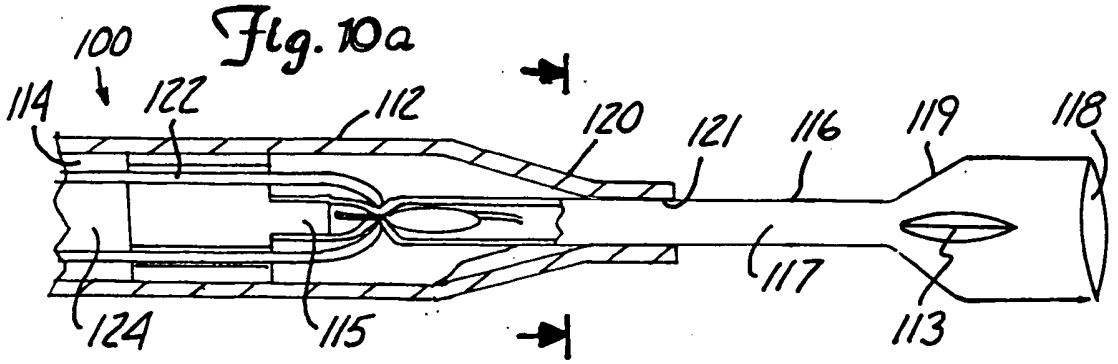


Fig. 10a

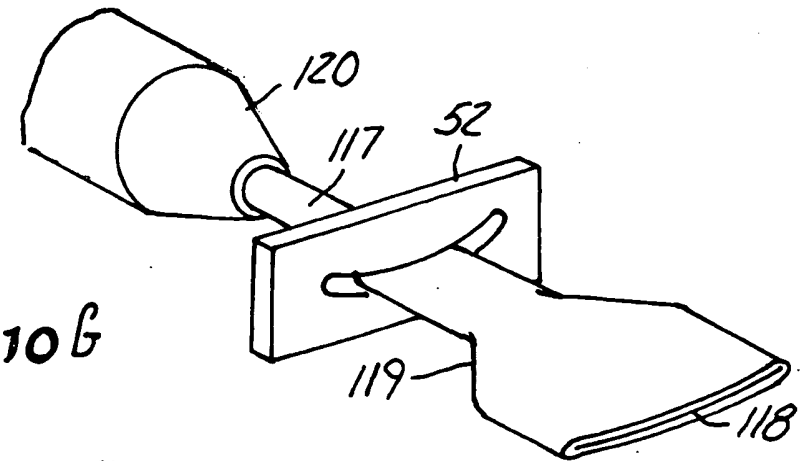


Fig. 10b

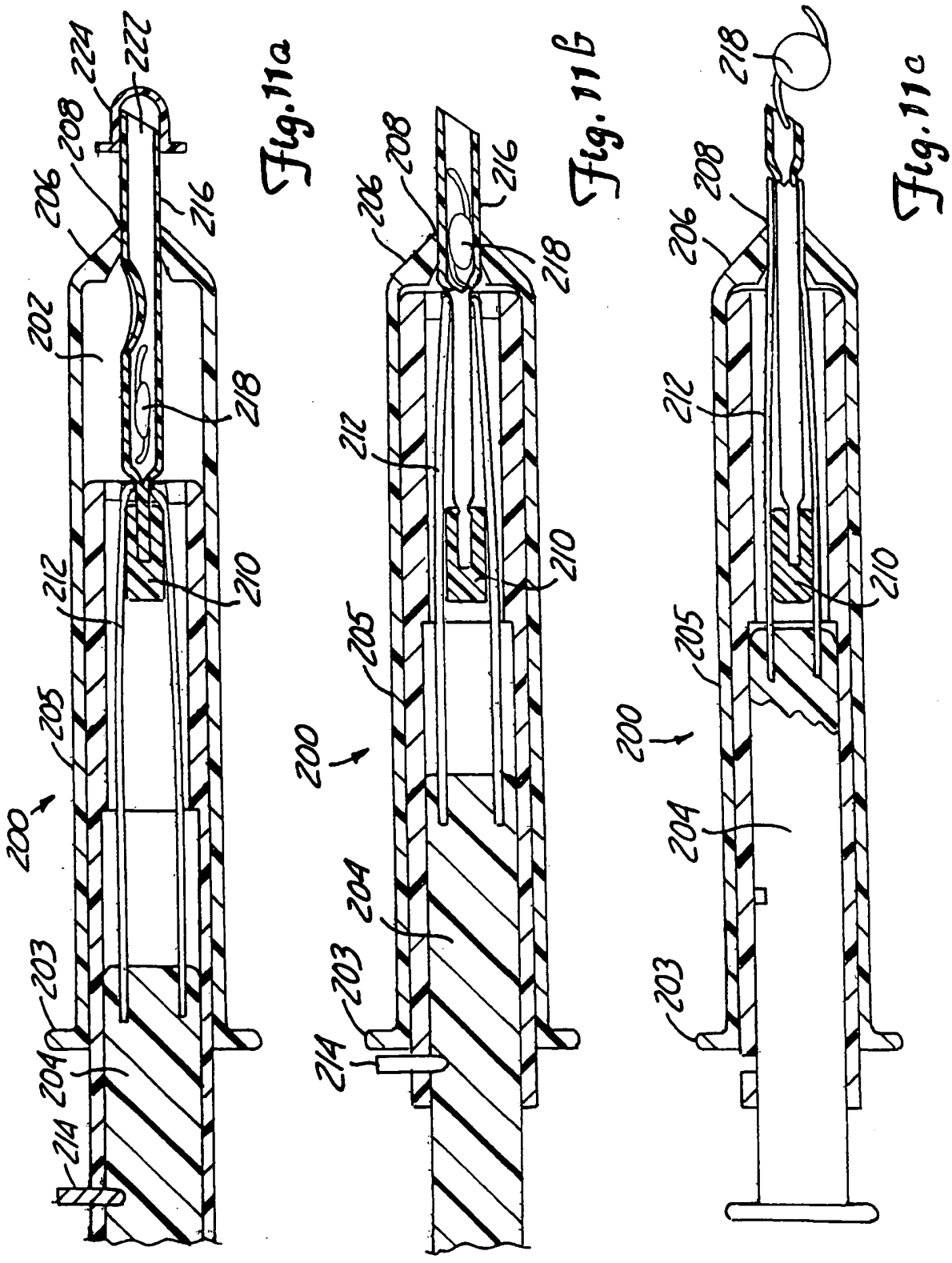

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Fig. 11a
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Fig. 11b
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Fig. 11c

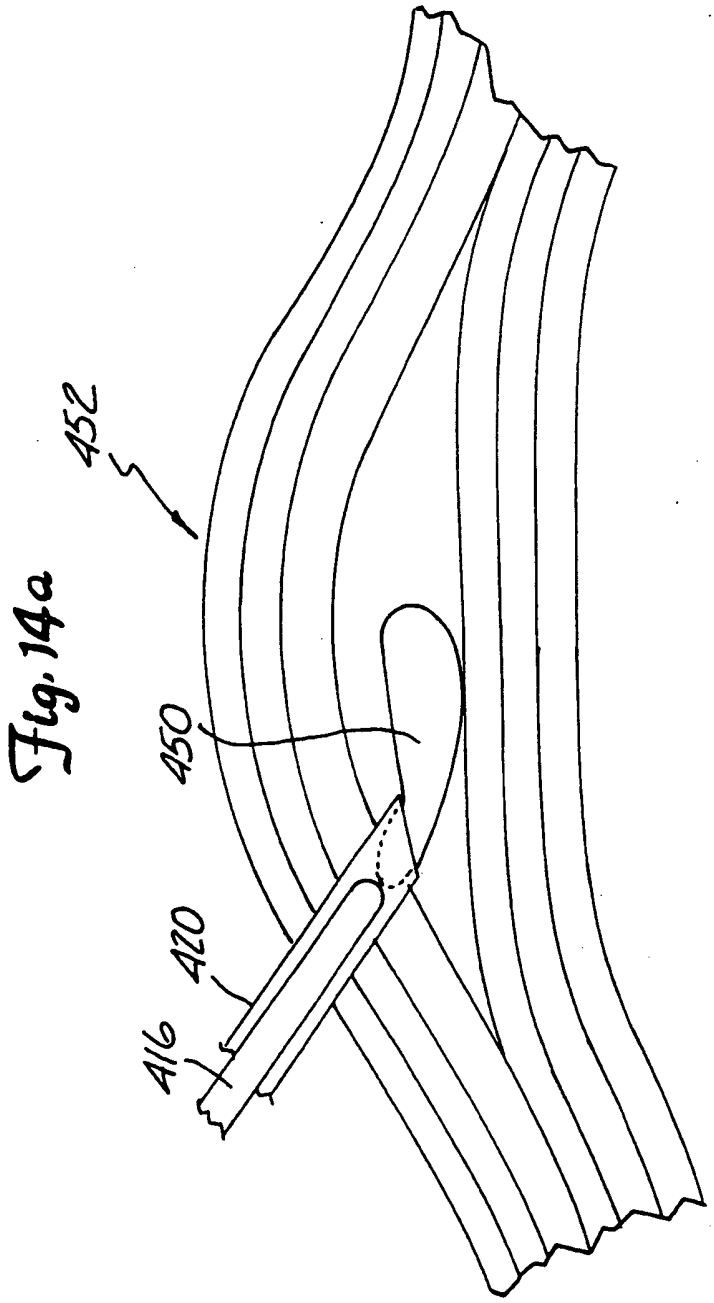


Fig. 14a

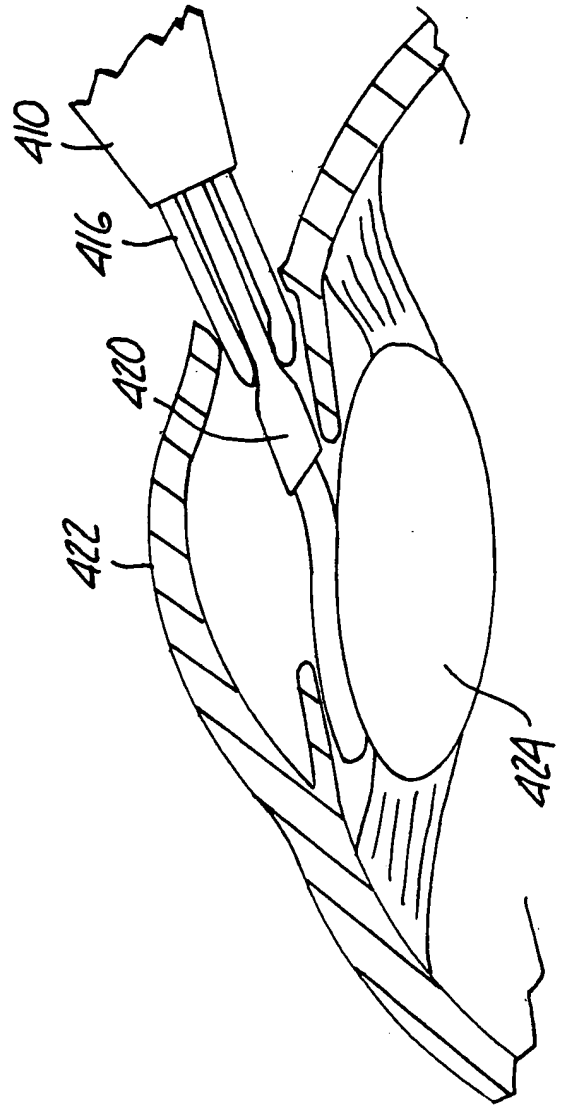


Fig. 14B

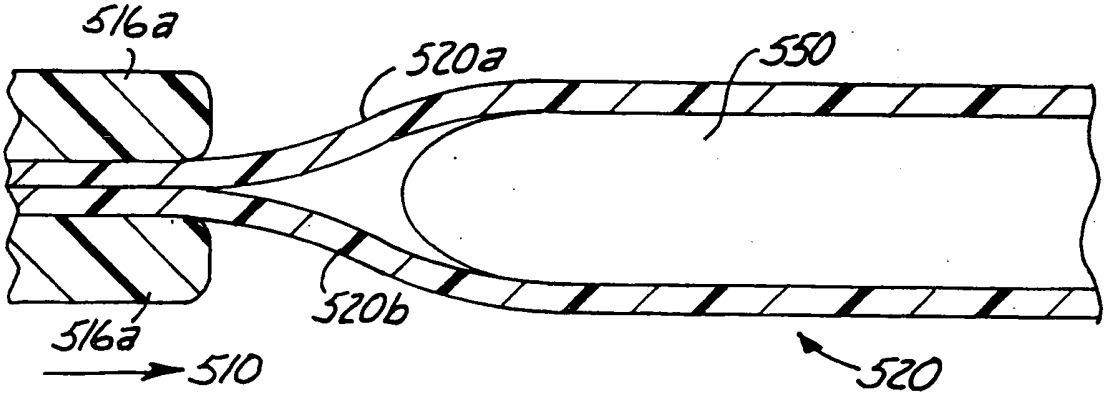


Fig. 15

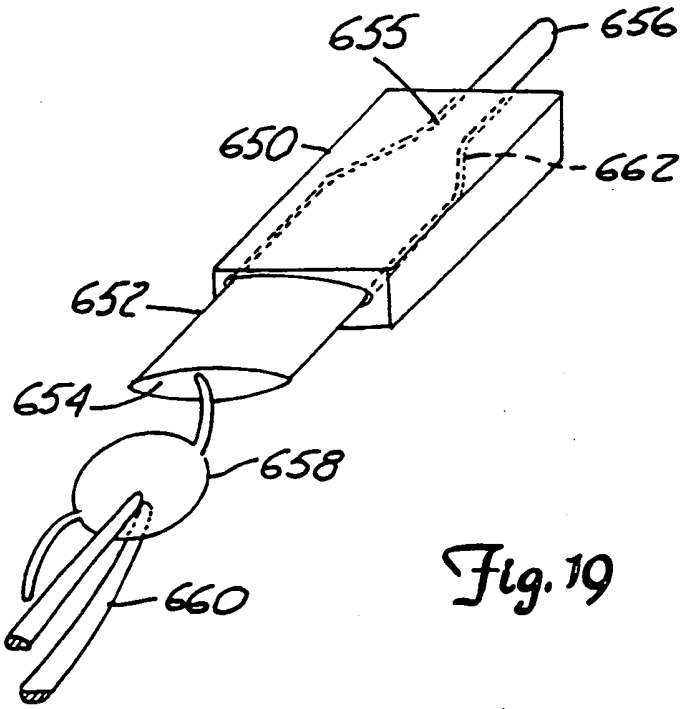


Fig. 19

Fig. 16b

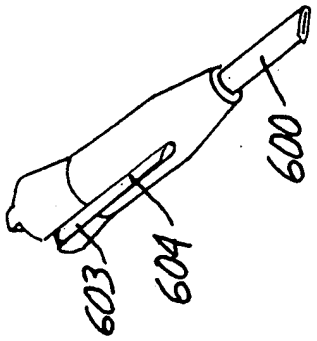


Fig. 16d

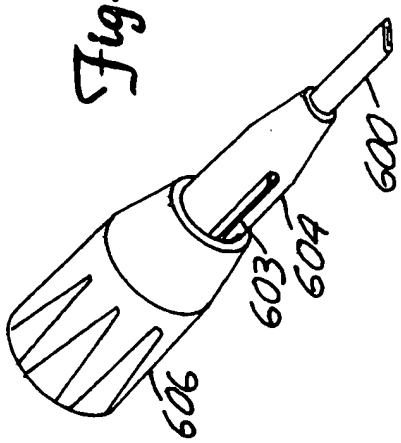


Fig. 16a

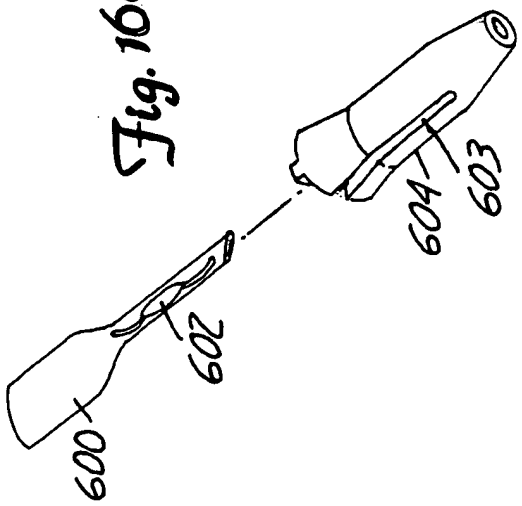
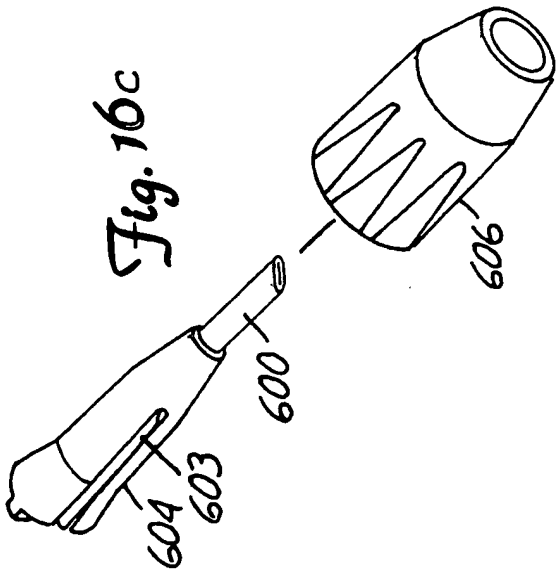


Fig. 16c



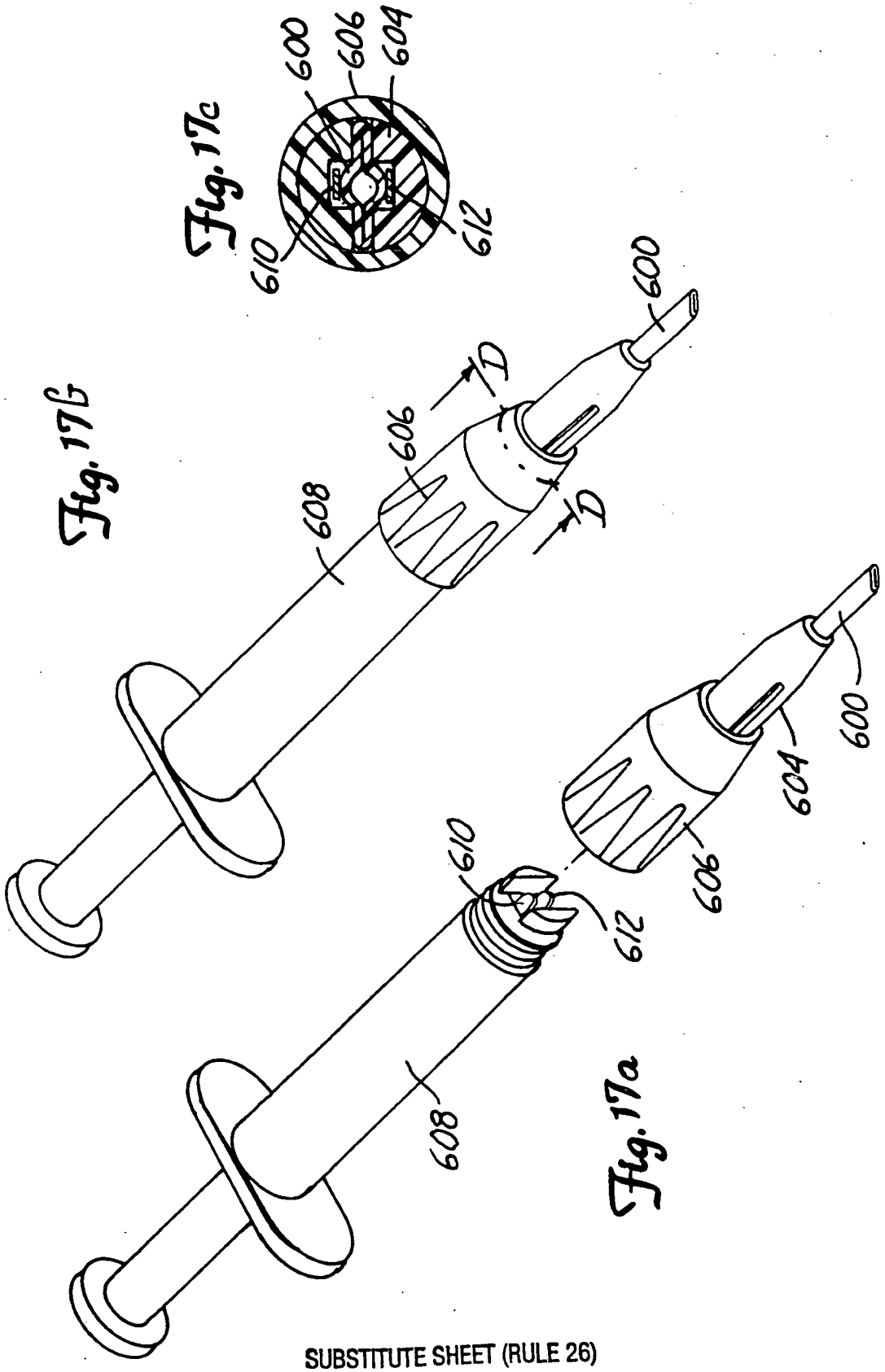


Fig. 17c

Fig. 17b

Fig. 17a

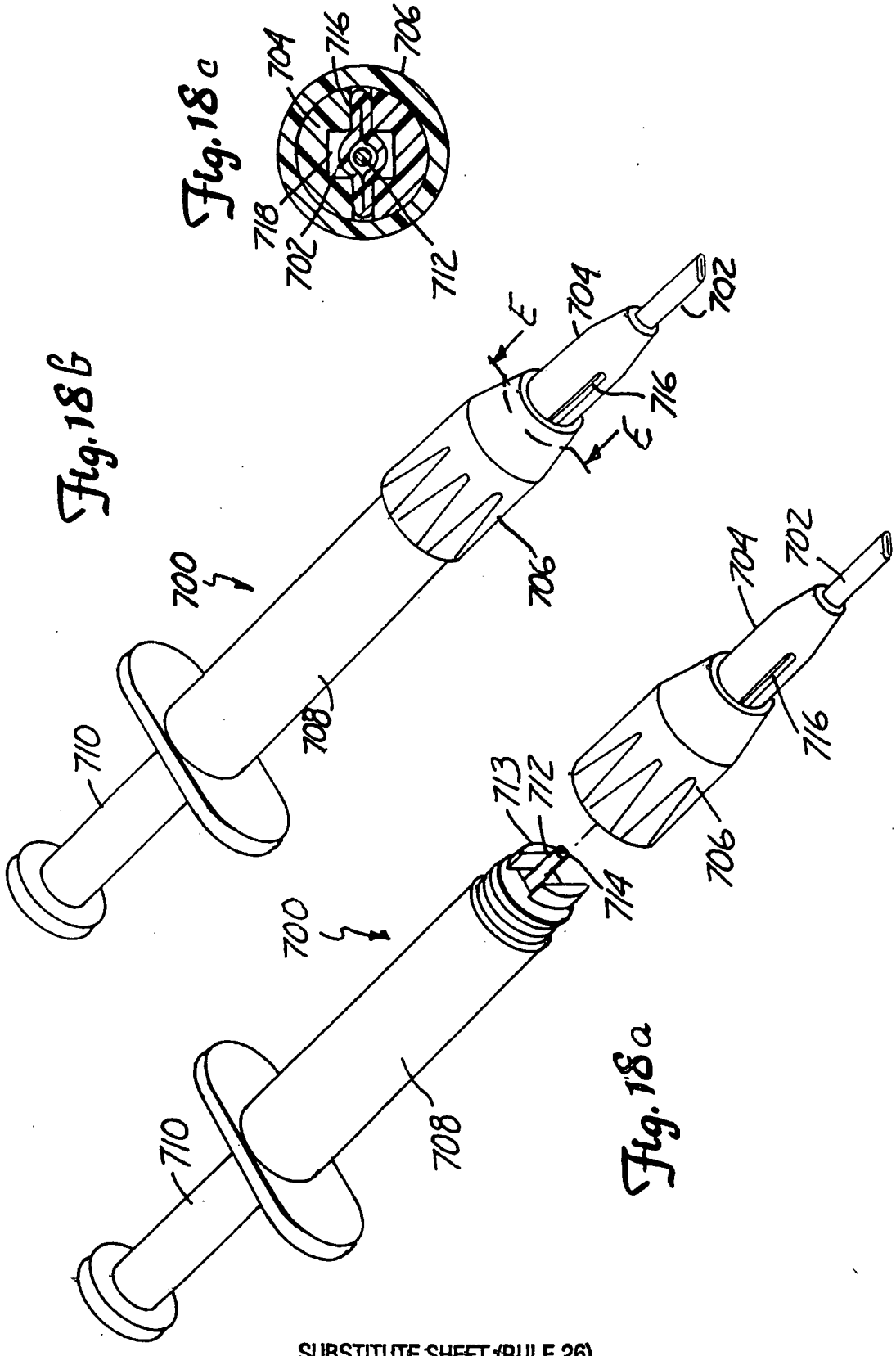


Fig. 18c
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Fig. 18b
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Fig. 18a

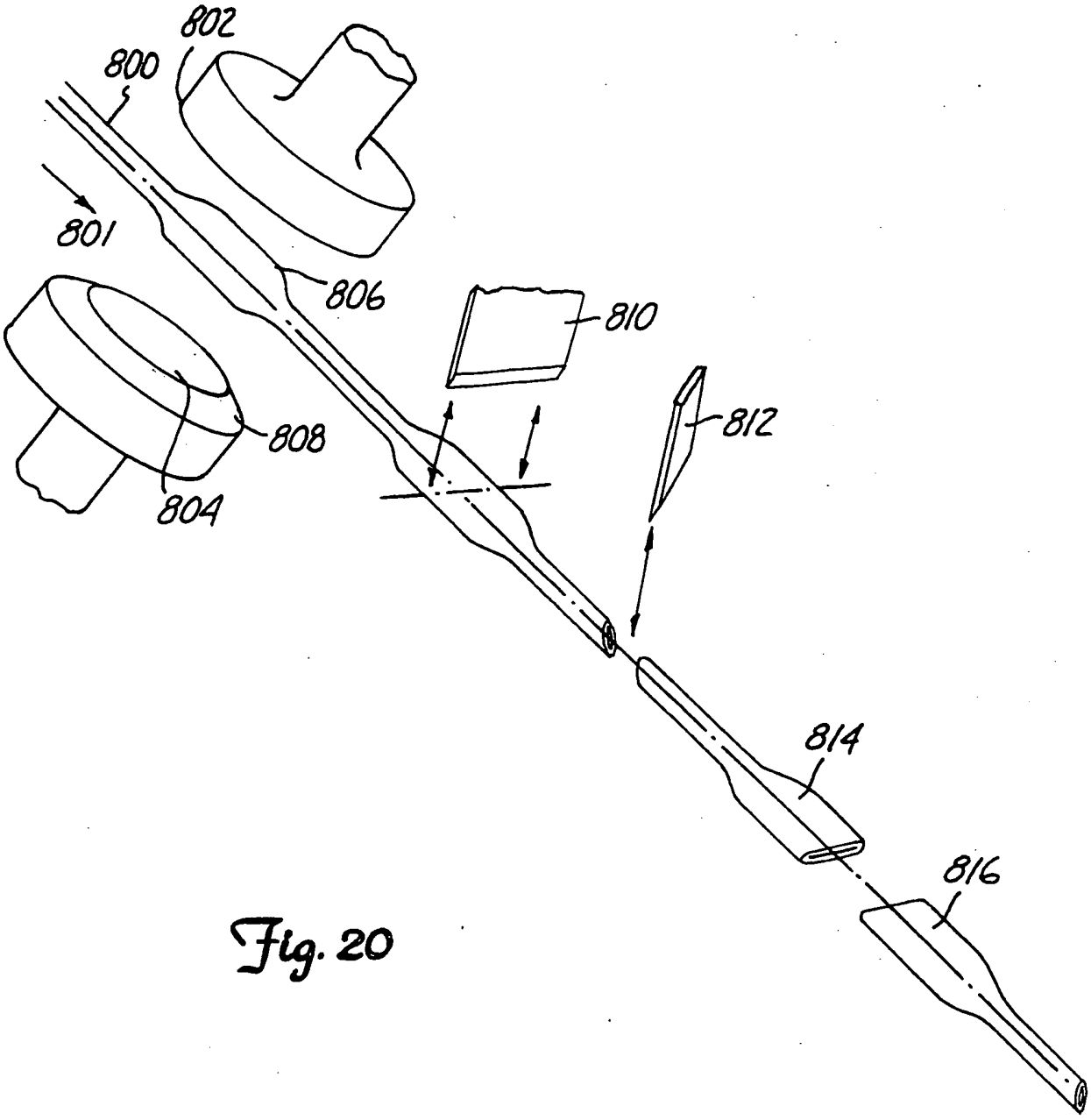

Fig. 20

INTERNATIONAL SEARCH REPORT

Interr ıal Application No
PCT/US 98/08303

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61J A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 791 689 A (BOONE R ET AL) 12 February 1974 see column 2, line 55 - line 64; figures see column 3, line 28 - line 35	1,2,4,7, 11,12
A	---	10,13,87
X	DE 42 36 210 C (OLYMPUS OPTICAL EUROP) 14 April 1994 see column 5, line 33 - line 53; figures 4,5	1,6,10
A	---	15,87
X	US 4 356 817 A (MCKIBBEN GARY E ET AL) 2 November 1982 see column 6, line 25 - line 53; figures	1,15,17
A	---	87
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 September 1998	12.01.99

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	NEUMANN, E

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inten ıal Application No
PCT/US 98/08303

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 578 020 A (MOSLEY MANUEL L) 26 November 1996 see abstract; claim 4; figures ---	1,7-10, 15
A	US 3 883 902 A (LYNCH HENRY W) 20 May 1975 see column 9, line 20 - column 10, line 8; figures see column 11, line 1 - line 12 -----	1-3, 11-13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/08303

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 81-86,88-90
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see annex

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-18,87

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

MULTIPLE INVENTIONS

1. Claims: 1-18,87

A device comprising a compressible sleeve to contain an implant and means for squeezing the sleeve to advance the implant from the sleeve.

2. Claims: 19-43

A device comprising a housing with a hand-piece having a lumen, means for stabilizing a compressible sleeve in the lumen and a pusher element.

3. Claims: 44-51

A compressible sleeve made from polymeric material and having two openings with different sizes and comprising an implant.

4. Claims: 52-55

A compressible sleeve made from polymeric material and having two openings with different sizes and a tapered portion which has a cross-sectional configuration selected from the group consisting of pleat(s), a V-shape, an oval, a circle and an envelope.

5. Claims: 56,57-60

A device comprising a pushing mechanism, a squeezing means to advance an implant in the device, a compressible sleeve and means for immobilizing the sleeve in the device.

6. Claims: 61-80

A device comprising a housing having two ends and an opening at one end, a compressible sleeve and a pushing mechanism conected to a squeezing blade which contacts the sleeve within the housing.

7. Claims: 91-96

A compressible sleeve having two openings with different sizes and wall thicknesses.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

8. Claims: 97,101-103

A compressible sleeve having two openings with different width and wherein the sleeve is made from a non-opaque material.

9. Claim : 98

A compressible sleeve having two openings with different width and wherein the sleeve is made from a non-opaque material and a sleeve holder made from rigid material and comprising a lumen having two openings with different sizes and wherein the lumen is adapted to conform to the shape of the sleeve.

10. Claims: 99,100

A sleeve supporting device made from rigid material and comprising a lumen having two openings with different sizes and wherein the lumen is adapted to conform to the shape of a sleeve.

11. Claims: 104-110

A device comprising a compressible sleeve having two openings with different width and wherein the sleeve is made from a non-opaque material and a hand-piece capable of mobilizing an implant and immobilizing the sleeve.

12. Claims: 111-113

A device comprising a compressible sleeve made from polymeric material, an implant positioned in the sleeve and a hand-piece having a push-rod that extends into the sleeve.

13. Claims: 114-118

A manufacturing method for a sleeve comprising the steps of positioning a tubing in a press with at least two compressive surfaces, applying a compressive force to the tubing to form and finally cut a distended and a non-distended portion in order to form a sleeve.

14. Claim : 119

An intraocular lens insertor comprising a compressible sleeve housing an intraocular lens wherin the lens is inserted in the sleeve before the sleeve is immobilized in the insertor.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

15. Claims: 120-124

A device comprising a compressible sleeve having two openings with different width and wherein the sleeve is made from a non-opaque material, an implant and a hand-piece having a push-rod that extends into the sleeve and means for advancing the push-rod to mobilize the implant in the device.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern al Application No
PCT/US 98/08303

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3791689 A	12-02-1974	NONE	
DE 4236210 C	14-04-1994	AT 161167 T	15-01-1998
		AU 5335894 A	24-05-1994
		DE 59307867 D	29-01-1998
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US 5578020 A	26-11-1996	NONE	
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